| UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORKx | |
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| NEW YORK STATE RESTAURANT ASSOCIATION, Plaintiff, | DECLARATION OF MARK W. MUSCHENHEIM IN OPPOSITION TO |
| -against- NEW YORK CITY BOARD OF HEALTH, NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE, and THOMAS R. FRIEDEN, In His Official Capacity as Commissioner of the New York City Department of Health and Mental Hygiene, | PLAINTIFF'S MOTION FO DECLARATORY AND PRELIMINARY INJUNCTIVE RELIEF |
| Defendants. | |
| X | 08 Civ. 1000 (RJH) |

MARK W. MUSCHENHEIM, declares under penalty of perjury that the following is true and correct:

- 1. I am an Assistant Corporation Counsel in the Office of Michael A. Cardozo, Corporation Counsel of the City of New York, attorney for defendants herein. This declaration is submitted in opposition to plaintiff's motion for declaratory and preliminary injunctive relief.
- 2. Attached hereto as Exhibit A is a copy of plaintiff's memorandum of law in support of its motion for declaratory relief and a preliminary injunction that was filed in New York State Restaurant Ass'n v. New York City Board of Health, # 07 Civ. 5710 (S.D.N.Y.) (RJH).
- 3. Attached hereto as Exhibit B is a copy of plaintiff's reply memorandum of law in support of its motion for declaratory relief and a preliminary injunction that was filed in New York State Restaurant Ass'n v. New York City Board of Health, # 07 Civ. 5710 (S.D.N.Y.) (RJH).

4. Attached hereto as Exhibit C is a copy of stipulation in in New York State Restaurant Ass'n v. New York City Board of Health, # 07 Civ. 5710 (S.D.N.Y.) (RJH) in which the parties agreed that the defendants' appeal of the Court's September 11, 2007 decision was deemed "dismissed as moot."

Dated: New York, New York February 8, 2008

> MICHAEL A. CARDOZO Corporation Counsel of the City of New York Attorney for Defendants 100 Church Street New York, New York 10007 (212) 442-0573

By:

Mark W. Muschenheim (MM 0498) Assistant Corporation Counsel



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| Defendants. | : | |

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF'S MOTION FOR DECLARATORY RELIEF AND A PRELIMINARY INJUNCTION

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MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF'S MOTION FOR **DECLARATORY RELIEF AND A PRELIMINARY INJUNCTION**

Preliminary Statement

The New York State Restaurant Association ("NYSRA") seeks an order enjoining the enforcement of a newly promulgated regulation, New York City Health Code Section 81.50 ("Regulation 81.50"), which dictates how a small percentage of New York City restaurants must communicate nutrition information to the public. The Regulation applies only to the small group of restaurants in New York City that have voluntarily decided to communicate nutrition information to their customers and the public. For these restaurants—and only these restaurants—the Regulation requires that one part of the nutrition information (caloric count) be isolated and displayed in a precisely prescribed manner on menus and menu boards.

Enforcement of Regulation 81.50 should be enjoined for two complementary but independent reasons. First, Regulation 81.50 is preempted by federal law. By its terms, the

Nutrition Labeling and Education Act (NLEA) subjects restaurants to regulations promulgated by the Food and Drug Administration (FDA) concerning "nutrition claims." Under those regulations, restaurants are not required to convey nutrition information to their customers. However, if they voluntarily choose to do so, they must comply with the regulatory regime promulgated by the FDA under the NLEA. Further, that federal statute expressly preempts state laws like Regulation 81.50, in which a State or local entity "directly or indirectly" establishes any requirement respecting nutrition claims that is "not identical" to the regulatory requirements of federal law. Because Regulation 81.50 imposes food labeling requirements different from (i.e. not "identical to"), the federal regulations, it is expressly preempted by the NLEA and void under the Supremacy Clause.

Second, Regulation 81.50 violates the First Amendment rights of plaintiff's members. The City's regulation forces these restaurants to change the content of the speech they convey on menu boards. The Regulation also forces the restaurants to undercut the message about nutrition that they already convey elsewhere. The City mandates that the restaurants convey the City's message-incomplete and out-of-context though it may be-in the precise manner and in the precise spot that the City thinks best. This is compelled speech. The Regulation violates the principle set forth by the Supreme Court in United States v. United Foods, Inc., 533 U.S. 405, 410 (2001), that even in the context of commercial speech, the government simply may not compel a speaker to convey a message the speaker does not want to convey.

In addition, Regulation 81.50 cannot survive even the more forgiving intermediate scrutiny set forth in Central Hudson Gas & Electric Corp. v. Public Service Comm'n of New York, 447 U.S. 557, 566 (1980). Under the doctrine of Central Hudson, the burden falls on the City (a) to identify a legitimate government interest, (b) show that the Regulation is effective in serving that interest, and (c) show that the Regulation is narrowly tailored to further the interest. The Board of Health contends that the Regulation will further the interest of public health by reducing the incidence of obesity in the general population. But Regulation 81.50 applies only to a small percentage of restaurants in New York City. It has caused some restaurants to stop providing nutrition information so as to avoid its onerous requirements. Other restaurants that might have begun to provide nutrition information have been discouraged. The City can make no case that the Regulation will have a plausible effect on obesity levels in the City. It passed the Regulation after only the most cursory investigation. In fact, it appears from recent statements made by the Department of Health that the Regulation is part of a social science experiment to determine whether requirements such as these have any effect, and if so, how much. Whatever value such experiments might have, plaintiff's members should not be forced to be the subjects, at the expense of their First Amendment freedoms.

Regulation 81.50 is unconstitutional. NYSRA seeks preliminary injunctive relief pursuant to Rule 65 forbidding defendants from enforcing Regulation 81.50, which violates the First Amendment freedoms of NYSRA's members. In addition, NYSRA seeks an expedited declaratory judgment under Rule 57 declaring Regulation 81.50 preempted by federal law.

FACTUAL BACKGROUND

A. NYSRA Members' Communication of Nutrition Information to Consumers in Accordance with Public Health Consensus and Federal Law

If there is a magic bullet to combat obesity in America, no one has found it. Recent governmental publications suggest that there is no one cause of obesity, that a web of factors acting together over time contribute to obesity, and that further study is needed, particularly in understanding how consumers use nutritional information. For example, the United States

Department of Agriculture focuses on four recommendations for combating obesity: (a) physical activity; (b) maintaining a balanced diet with proportionality, variety and moderation; (c) nutrient-dense foods containing calcium, potassium, fiber, magnesium and Vitamins A, C and E; and (d) limited intake of sodium and alcoholic beverages. See USDA's "Dietary Guidelines for Americans" (2005) (attached to the Appendix to this Memorandum ("Appendix") at Tab A); Demuth Decl. ¶¶ 16, 18.

Recently, the Food and Drug Administration asked The Keystone Center for Science and Public Policy to design, convene, and facilitate a forum seeking collaborative solutions in the area of away-from-home foods. The Keystone Forum's final report (May 2006), concluded that there is no public health consensus on how consumers use nutrition information:

> There is a clear need for more research regarding how the provision of nutrition information, claims (such as "low calorie"), and symbols influence consumer preference and choice for awayfrom-home food consumption situations. Of particular concern is how, when, and why consumers use nutrition information and claims during their decision-making processes. More specifically, a better understanding is needed of the types of factors that moderate consumers' responses to the provision of nutrition information and claims for away-from-home foods.

The chapter concludes with a list of suggested research questions for addressing these topics.

The legislative and regulatory environment (described below) confirms that the federal government has made a determination that the effective communication by restaurants of nutrition information to customers is a complex and uncertain subject; that there is no one "right way" to communicate this information; that restaurants should be permitted and encouraged to

The Keystone Center, The Keystone Forum on Away-From-Home Foods: Opportunities for Preventing Weight Gain and Obesity, Final Report, May, 2006, at 13, available at http://www.keystone.org/spp/documents/Forum Report FINAL 5-30-06.pdf (last visited June 13, 2007).

try different ways of communicating; and that they should not be burdened by specific requirements that would hinder experimentation. Congress has given the FDA plenary authority over the nutrition content claims voluntarily made by restaurants (e.g., "contains 100 calories"). The FDA, in turn, has given restaurants flexibility in determining whether and how to communicate such claims. The NLEA prohibits states from imposing any different or additional requirements. (See infra at 11-16).

Against this backdrop, some restaurants in New York City voluntarily publish comprehensive nutrition information about the food items they sell. They publish this information in order to assist their customers to make healthful and appropriate food choices. Realizing that consumers have individual dietary needs and restrictions, these restaurants consistent with the views of the public health community—believe that the best way to serve their customers is to provide them with a complete nutritional breakdown of their menu items one that includes factors such as fat, saturated fat, dietary fiber, sugar, cholesterol, protein, carbohydrate, sodium, and vitamin and mineral content, as well as recommended percentages of daily consumption values and calories. Such restaurants provide comprehensive nutritional information through websites, brochures, on-package labeling, posters, and tray liners. Customers have the opportunity to compare and contrast the nutritional content of various food items which, these restaurants believe, leads to more informed choices based on each consumer's individual needs.

B. Promulgation of New York City Health Code § 81.50

After just one day of hearings—most of which focused on a regulation not at issue here the New York City Department of Health and Mental Hygiene ("Department of Health") determined that it had found the "right way" for restaurants to communicate with their customers

and decided to impose that way on a small fraction of the restaurants in New York City. On December 5, 2006, the Department of Health adopted Regulation 81.50 (copy attached at Appendix Tab D), which compels a small group of restaurants in New York City that have voluntarily decided to communicate nutrition information to their customers and the public to isolate and display one part of that nutrition information (caloric count) in a precisely prescribed manner on menus and menu boards. The Regulation, which becomes effective on July 1, 2007, applies only to those restaurants that voluntarily provided calorie information to the public as of March 1, 2007. In addition, the Regulation applies only to those menu items that are standardized with regard to portion size, formulation, and ingredients. According to the Department of Health, only ten percent of New York City restaurants meet these criteria and will be subject to the Regulation's requirements.

The Regulation prescribes the precise manner in which calorie counts must be displayed. Under the Regulation, menu boards and menus must list the calorie content value next to each menu item. See 24 RCNY Health Code § 81.50(b). "The term 'calories' or 'cal' shall appear as a heading above a column listing the calorie content value of each menu item, or adjacent to the calorie content value for each menu item, in the same or larger typeface as the calorie content values for individual menu items." Id. § 81.50(b)(1). The Regulation mandates the size and typeface that the restaurant must use to present the caloric value of an item. In the case of menu boards, "calorie content values [must] be posted in a size and typeface at least as large as the name of the menu item or price, whichever is larger," Id. § 81.50(b)(1)(A). In the case of printed menus, the Regulation requires that "calorie content values . . . be legible and . . . printed in a size and typeface at least as large as the name or price of the menu item." Id. § 81.50(b)(1)(B).

C. Detrimental Effects of Regulation 81.50

NYSRA believes that Regulation 81.50 will undermine its members' nutrition objectives and interfere with their ability to communicate effectively with their customers. Displaying calories in isolation will inaccurately overemphasize the importance of calories to a wellbalanced diet, and neglect the relevance of other important nutrients and other contributing causes of obesity. Forcing restaurants to highlight calories in isolation from other nutrients increases the risk that consumers will ignore other nutritional information that restaurants would like to provide to them. In addition, studies have shown that most consumers do not know the significance of a particular calorie count. See, e.g., Haugen Decl. ¶ 5 and the International Food Information Council Foundation Food and Health Surveys for 2006 and 2007 (copies attached at Appendix Tabs B and C, respectively); Demuth Decl. ¶ 17. So, for them, it is of limited use to provide the caloric values of particular food items alone, without also informing them what the daily recommended caloric levels of a healthy diet are.

Menu boards are the most valued space in the restaurants that offer standardized food items and thus are subject to the Regulation. See Munoz Decl. ¶ 3; Colón Decl. ¶¶ 3-5. Available space on the menu boards is already very limited. Adding calorie information will result in menu boards that are cluttered and that in all likelihood will need to use very small font sizes. This will make menu boards confusing and difficult for consumers to read, directly interfering with the ability of such restaurants to communicate with their customers. See Liewen Decl. ¶ 10; Richardson Decl. ¶ 6; Munoz Decl. ¶ 5 & 6.

Regulation 81.50 has established a rigid and irrational regime. Although the Regulation provides that the Department of Health can accept alternatives to posting on menu boards, the Department has nonetheless rejected reasonable alternatives such as counter mats at the point of

purchase or signs on stanchions. See Colón Decl. ¶ 8 &9; Horn Decl. ¶ 4. The City has determined that Regulation 81.50 applies only to menu boards, and not to menu listings on cards in glass cases. See Horn Decl. ¶ 4. It has determined that a restaurant can comply by listing a 'range' of calories for menu items that vary, even if that range is so great as to make the disclosure meaningless (e.g., "contains 40 to 400 calories"). See Liewen Decl. ¶ 9, 11 &12; Burnett Decl. ¶ 6.

Regulation 81.50 has chilled the speech of some NYSRA members by imposing burdensome conditions on speech. Some NYSHA members previously published nutrition information on their websites and in stores, but as of March 1, 2007 abandoned disclosure of nutrient information rather than attempt compliance with the Regulation. See Burnett Decl. ¶ 4; Richardson Decl. ¶ 4.

ARGUMENT

NYSRA seeks a declaratory judgment declaring Regulation 81.50 to be preempted by federal statute and regulation and therefore in violation of the Supremacy Clause of the United States Constitution. NYSRA also seeks a preliminary injunction precluding defendants from violating the First Amendment rights of its members by enforcing the Regulation.

I. NYSRA IS ENTITLED TO A JUDICIAL DECLARATION THAT FEDERAL LABELING LAW PREEMPTS REGULATION 81.50

Under the Supremacy Clause, Congress may preempt any state law that conflicts with the exercise of federal power. "Pre-emption fundamentally is a question of congressional intent . . . and when Congress has made its intent known through explicit statutory language, the courts' task is an easy one." See English v. General Elec. Co., 496 U.S., 72, 78-79 (1990) (citation

omitted). Federal regulations "have no less a pre-emptive effect than federal statutes." Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta, 458 U.S. 141, 153 (1982).

To determine whether Regulation 81.50 is preempted, the Court follows a wellestablished two-step analysis, deciding (i) whether NYSRA members' presentation of calories and other food nutrients are governed by federal law; and (ii) if so, whether that federal law expressly or impliedly preempts Regulation 81.50. See, e.g., Sprietsma v. Mercury Marine, 537 U.S. 51, 56 (2002); Geier v. American Honda Motor Co., 529 U.S. 861, 867 (2000). Because the answer to both questions is yes, Regulation 81.50 must be declared void.

Caloric Labeling of Food Is Subject to the Nutrition Labeling A. and Education Act

Congress enacted the Nutrition Labeling and Education Act (NLEA) in 1990. See 21 U.S.C. §§ 343, 343-a (copy attached at Appendix Tab E). The NLEA governs two related areas: subsection (q) imposes mandatory food labeling requirements for packaged foods. Packaged foods must, for example, bear a label that identifies serving size, number of servings per package, and certain nutrition information in a detailed format mandated by the FDA. Subsection (r) gives the FDA regulatory authority over more general nutrient and health benefit "claims" associated with food, such as "contains 100 calories." 21 U.S.C. §§ 343(q), (r); 21 C.F.R. § 101.13(b)(2). Pursuant to the grant of authority in subsection (r), the FDA has enacted extensive rules regarding labels and claims associated with food. See 21 C.F.R. Part 100.

Restaurants are partially exempt from this regime. Restaurants are wholly exempt from the food labeling requirements of subsection (q). 21 U.S.C. § 343(q)(5)(A)(i). But subsection (r), concerning nutrient claims, contains only a limited exemption for restaurants. Under subsection (r), any nutrient content claim—if it is voluntarily made by the restaurant—must be

made in accordance with regulations promulgated by the FDA. 21 U.S.C. § 343(r)(2)(A)(i). Restaurants are exempt only to the extent that they make claims relating to (1) cholesterol, (2) saturated fat, (3) dietary fiber, or (4) nutrients that increase the risk of disease. 21 U.S.C. § 343(r)(5)(B). Under the applicable regulations, restaurants choose whether to opt into the general nutrition claim and labeling scheme promulgated under subsection (r). See 21 C.F.R. § 101.9(j)(2)(i) (regulations apply unless the food served "bears no nutrition claims or other nutrition information in any context on the label or in the labeling or advertising").

Restaurants that voluntarily disclose nutrient information about menu items (including the caloric value of food) through food labeling, such as billboards, brochures in restaurants, and restaurant internet websites, are subject to the NLEA's food labeling regime. Because statements about calories are "nutrient content claims" within the meaning of the NLEA, they are governed by regulations promulgated by the FDA under authority of subsection (r). See 21 C.F.R. § 101.13(b)(2) (stating that a nutrient claim is "any direct statement about the level or range of a nutrient in food," such as "contains 100 calories").

For restaurants subject to the NLEA, the FDA has promulgated a special rule. 21 C.F.R. §101.10 (1996) (copy attached to Appendix at Tab F).² Unlike other kinds of food labeling, the

Footnote continued on next page

The FDA promulgated this regulation in 1996. During the notice and comment period for Regulation 81.50, the Department of Health relied on an outdated statement by the FDA (issued in 1995) to dismiss concerns about preemption. According to the Department, this 1995 statement supported its position that nutrition claims on restaurant menus were exempted from the requirements of the NLEA. See New York City Department of Health and Mental Hygiene, Summary and Response to Public Hearing and Comments Received Regarding Amendment of Article 81 of the New York City Health Code Adding a New Section 81.50 to Require Labeling on Menus and Menu Boards, at 11 (Nov. 27, 2006) (copy attached to Appendix at Tab G) (citing statement in a 1995 FDA publication that "claims on menus are not currently subject to NLEA.") (Food and Drug Administration, US DHHS, Public Health Service, Food Labeling: Questions and Answers, Volume II, "A Guide for Restaurants and Other Retail Establishments" (hereinafter "FDA Q&A Vol. II") (copy attached to Appendix at Tab H), Question/Answer Number 31 at 10 (August 1995)).

FDA gives restaurants broad freedom to present accurate information concerning nutrient claims in any reasonable manner. The FDA's nutrition claim and labeling requirements for restaurants provide, in part:

Nutrition labeling in accordance with § 101.9 [specifying nutrition facts required on labels] shall be provided upon request for any restaurant food or meal for which a nutrient content claim . . . is made, except that information on the nutrient amounts that are the basis for the claim (e.g., "low fat, this meal provides less than 10 grams of fat") may serve as the functional equivalent of complete nutrition information as described in § 101.9. Nutrient levels may be determined by nutrient data bases, cookbooks, or analyses or by other reasonable bases that provide assurance that the food or meal meets the nutrient requirements for the claim. Presentation of nutrition labeling may be in various forms, including those provided in § 101.45 [concerning certain unprocessed foods] and other reasonable means.

21 C.F.R. § 101.10 (emphasis added). Thus, the FDA has given restaurants great flexibility to decide how to communicate nutrient information to customers. For example, a restaurant may communicate nutrition information through in-store signs, posters, brochures, notebooks or charts, as contemplated in 21 C.F.R. § 101.45. Restaurants also may communicate nutrition claims through various "Nutritional Facts" formats set out in 21 C.F.R. § 101.9. But these options are not exclusive. Section 101.10 allows restaurants to provide information through "other reasonable means" as well.

Footnote continued from previous page

It is true that, as of 1995, the FDA considered restaurant menus to be completely exempt from the NLEA. But soon after the FDA published its 1995 statement, the blanket exemption under the NLEA for restaurant menus was held to violate the NLEA. See Public Citizen, Inc. v. Shalala, 932 F. Supp. 13, 18 (D.D.C. 1996). Consistent with that decision, the FDA revised its regulations to acknowledge that nutrient claims on restaurant menus were not exempt, and instead fell within the coverage of the statute. See 61 Fed. Reg. 40320-01 (Aug. 2, 1996) (final rulemaking revising regulations: reversing earlier rule that had completely exempted restaurant menus from the requirements for nutrient content claims and health claims). As of 1996, the FDA acknowledges that the NLEA covers nutrient and health claims (including caloric content) on restaurant menus.

In short, there can be no doubt that restaurant disclosure of calories is governed by federal law and that the federal law grants restaurants freedom to choose among a variety of formats in displaying the information.

Document 31

B. The NLEA Expressly Preempts Non-Identical State or Local Law

State law is expressly preempted when "Congress' command is explicitly stated in the statute's language." FMC Corp. v. Holliday, 498 U.S. 52, 56-57 (1990) (internal quotations omitted). When an express preemption provision exists, a determination of its scope begins with "the plain wording of the clause, which necessarily contains the best evidence of Congress' preemptive intent." In re WTC Disaster Site, 414 F.3d 352, 372 (2d Cir. 2005) (citation omitted).

Here, Congress has preempted state laws that are not "identical to" the requirements of section 343(r) and FDA regulations promulgated thereunder. The preemption statute provides, in part:

> no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce —

> > * * * * *

(5) any requirement respecting any claim of the type described in section 343(r)(1) of this title, made in the label or labeling of food that is not identical to the requirement of section 343(r) of this title, except a requirement respecting a claim made in the label or labeling of food [by restaurants concerning cholesterol, saturated fat and dietary fiber and nutrients that increase the risk of disease,] which is exempt under section 343(r)(5)(B).

21 U.S.C. § 343-1(a)(5) (emphasis added) (copy attached at Appendix Tab I).³

Subsection (q) also has an associated express preemption provision, 21 U.S.C. § 343-1(a)(4), but it does not cover restaurants because they are exempt from the requirements of subsection Footnote continued on next page

There can be no doubt that Regulation 81.50 imposes requirements "respecting any claim of the type described in section 343(r)(1)" because publishing calorie content is a nutrition claim under that section. See 21 U.S.C. § 343(r)(1); 21 C.F.R. § 101.13(b)(2). And Regulation 81.50 imposes requirements not "identical" to those of the federal law and its accompanying regulations, 21 C.F.R. § 101.10.

Under the FDA's implementing regulations, the prohibition against state laws not "identical to" the federal requirements extends to any state requirement that —

> directly or indirectly imposes obligations or contains provisions concerning the composition or labeling of food, or concerning a food container, that:

- (i) Are not imposed by or contained in the applicable provision (including any implementing regulation) of $\{\S\S 343(q) \text{ or } (r)\}$; or
- (ii) Differ from those specifically imposed by or contained in the applicable provision (including any implementing regulation) of [§§ 343(q) or (r)].

21 C.F.R. § 100.1(c)(4) (copy attached at Appendix Tab J).

Two federal district courts have interpreted the term "not identical to" as used in two subsections of Section 343-1(a). See Reyes v. McDonald's Corp., 2006 WL 3253579, at *4 (N.D. III. Nov. 8, 2006) (construing section 343-1(a)(5)); and Vermont Pure Holdings, Ltd. v. Nestle Waters North America, 2006 WL 839486, at *5 (D. Mass. March 28, 2006) (construing section 343-1(a)(1)). Both courts followed the preemption analysis set forth in Bates v. Dow

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⁽q). In addition, section 343-1(b) contains an exception that gives States the right to petition the FDA to exempt certain non-identical state and local requirements from preemption. 21 U.S.C. § 343-1(b); see also 21 C.F.R. § 100.1 (implementing subsection 343-1(b)). The Department of Health has never sought or been granted an exemption for Regulation 81.50 pursuant to this procedure.

Agrosciences LLC, 544 U.S. 431 (2005). In Bates, the Supreme Court analyzed the preemption provision of a federal labeling statute. The preemption provision applicable there provided that states "shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter." Bates, 544 U.S. at 436 (quoting 7 U.S.C. § 136v(b)) (emphasis added). The Court in Bates concluded that the plain language of the preemption statute meant that a state labeling law would be preempted if (i) the state law is a requirement for "labeling or packaging;" and, if so, (ii) it imposes a requirement "in addition to or different from those required" under federal law. 544 U.S. at 444 (internal quotations omitted) (emphasis in original). Conversely, state law could avoid preemption only if it were "equivalent to and fully consistent with" federal law. Id. at 447. To determine equivalency and consistency, the Bates court instructed lower courts to measure state law requirements against standards found in the statutes as well as relevant "regulations that give content to [the statute]." Id. at 453.

The courts in Reyes and Vermont Pure applied the preemption test of Bates, replacing the language of the federal act at issue in Bates, "in addition to or different from" with the even stricter phrase "identical to" found in the applicable statute here, Section 343-1(a)(5). See Reyes, 2006 WL 3253579, at *5-6; Vermont Pure, 2006 WL 839486, at *5. These courts applied the plain language—"identical to"—so that state law was preempted unless it had "substantially the same language as the comparable provision" of federal law. Vermont Pure, 2006 WL 839486, at *5 (quoting H.R. Rep. No. 109-379 (Feb. 28, 2006)). In Goya de Puerto Rico, Inc. v. Santiago, 59 F. Supp. 2d 274, 279 (D.P.R. 1999) (decided six years before Bates), the court considered whether the Puerto Rico Department of Agriculture requirement for the labeling of pigeon peas was preempted by subsection 343-1(a)(2), a provision analogous to the one at issue here. The

Puerto Rican regulation required that the name and address of both the canner and importer be printed on the label, whereas the subsection 343(e) gives businesses discretion to choose whether to include on the label the name and place of business of the importer, packer, or distributor. Id. at 280. The court in Goya de Puerto Rico found the Puerto Rican law preempted, reasoning that the federal law "was quite clear about the kind of information that state labeling laws could require." Id. Precisely the same reasoning applies to this case.

Section 101.10 of Title 21 of the Code of Federal Regulations, which is the FDA regulation implementing the relevant provisions of the NLEA, allows restaurants to decide which "reasonable means" is best suited to convey nutrient claims to customers. Indeed, the FDA specifically stated that Section 101.10 does not require food labeling to be in a particular format;

Question:

FDA's requirement for the Nutrition Facts format are fairly specific with respect to type style, type size, and placement. Does the agency have similar requirements for nutrition labeling of restaurant foods?

Answer:

It depends on the format used. Nutrition labeling for restaurant foods may be presented in various formats, including Nutrition Facts (§ 101.9), following the format established for raw fruit, vegetables, and fish (§ 101.45), and by other reasonable means (e.g., a statement such as "low fat, this food contains no more than 3 grams of fat" in a brochure or notebook) (§ 101.10).

Consistent with its flexible approach towards restaurant food labeling, FDA has not established standardized type size or placement requirements in § 101.10. Labeling that is easily accessible to consumers, that contains all required nutrition information, and that is presented clearly and legibly, would be generally consistent with the "reasonable means" provision of § 101.10.

FDA Q&A Vol. II, Question/Answer Number 80, at 24 (emphasis added) (Appendix Tab H). See also infra at 16-17.

Regulation 81.50 imposes mandatory nutrient disclosure requirements where the federal regulation does not. Regulation 81.50 restricts the flexibility that the FDA provided to restaurants. It requires that certain nutrition information (calories) be isolated from other nutrition information and presented in a particular format (on the restaurant menus and menu boards), in a particular font size (equal to the larger of the menu item or price). These content and presentation requirements are not "identical" to those of the NLEA or of the FDA's regulations promulgated thereunder, Section 101.10.

C. The NLEA Impliedly Preempts Regulation 81.50

Even when Congress has not expressly displaced state laws, state law is impliedly preempted "to the extent that it actually conflicts with federal law." In re WTC Disaster Site, 414 F.3d at 372. Such "conflict" preemption occurs where the "state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Id. (citation omitted). Such preemption occurs when the state law stands as an obstacle to the full implementation of the federal regulatory plan, even if state law shares the same goals as the competing federal law. International Paper Co. v. Ouellette, 479 U.S. 481, 494 (1987); accord Perez v. Campbell, 402 U.S. 637, 650-52 (1971). Implied preemption may arise from federal regulations implementing federal statutes, see Bates, 544 U.S. at 452, and even when the statute at issue also contains an express preemption clause that does not apply, see Geier, 529 U.S. at 872-74. Here, because Regulation 81.50 directly interferes with the flexibility chosen by the FDA to encourage restaurants to provide nutrient information, it is impliedly preempted.

Through the flexibility provided in Section 101.10, the FDA encourages restaurants to give consumers accurate and complete nutrition information and to encourage product innovation through the development and marketing of improved foods. See 58 Fed. Reg. 2302-

provide such information on the menu or menu board.") (copy attached at Appendix Tab K).

Rather, the federal policy is, expressly, one of flexibility.⁵

Dr. Mark B. McClellan, Commissioner of Food and Drugs, established the Obesity Working Group in 2003 to prepare a report that outlines an action plan to address the obesity problem from FDA's perspective and authorities. The FDA Center for Food Safety and Applied Nutrition publishes periodic Questions and Answers addressing issues raised in the report.

Without a ruling that inconsistent state and municipal laws, such as the New York City regulation, are preempted, restaurants could ultimately be subject to hundreds of different regulatory regimes, which is exactly what Congress and the FDA did not want to happen. Many states and localities already have pending legislation that would impose new requirements on restaurants and that differ from the NLEA. See, e.g., S.B. 120, 2007 Reg. Sess. (Cal. 2007); H.B. 54, 24th Leg. (Haw. 2007); H.B. 389, 95th Gen. Assem. (III. 2007); S.B. 1290, 185th Sess. (Mass. 2007); S. 2264, 213rd Leg. (N.J. 2006); City of Philadelphia, Bill No. 070153 (March 1, 2007).

The Supreme Court has repeatedly held that, when federal law implements federal policies by explicitly affording regulated entities a choice of options, states may not limit them. See, e.g., Geier, 529 U.S. at 875, 881. In Geier, the Supreme Court held that federal regulations implementing federal car safety standards for passive restraint devices preempted negligence claims based on state product liability laws. See Geier, 529 U.S. at 881. The Court reasoned that because the federal car safety standards "deliberately provided the manufacturer with a range of choices among different passive restraint devices" in order to foster experimentation and innovation in the development of passive restraint devices, the plaintiff's tort claim, in seeking to limit that range of choice to driver's side airbags, was impliedly preempted. Id. at 875, 881.

Here, the requisite direct interference with the federal regulatory program exists. As noted above, the FDA afforded restaurants a range of presentation options under Section 101.10 to further the NLEA's objectives of allowing restaurants to determine how best to present nutrition information. *See de la Cuesta*, 458 U.S. at 154-56 (finding that state common law rule which limited the use of "due on sale" clause in mortgage contract cases whereas federal regulation specifically allowed a savings and loan the flexibility to enforce such a clause "at its option" created "an obstacle" to the federal regulation and was therefore preempted) (internal quotations omitted). Courts give significant weight to explicit statements of the federal agencies favoring a choice of options. *See, e.g., Geier*, 529 U.S. at 883 (stating that the federal agency's views of its own regulations "should make a difference").

11. THE COURT SHOULD GRANT A PRELIMINARY INJUNCTION TO PROTECT THE FIRST AMENDMENT RIGHTS OF NYSRA'S **MEMBERS**

Under Rule 65, a plaintiff can obtain a preliminary injunction against infringement of constitutional rights by the State. See Green Party of New York State v. New York State Bd. of Elections, 389 F.3d 411, 418 (2d Cir. 2004). A preliminary injunction is proper where a plaintiff shows (a) irreparable harm, and (b) a likelihood of success on the merits. Id.; Long Island R.R. Co. v. International Ass'n of Machinists, 874 F.2d 901, 910 (2d Cir. 1989); see International Dairy Foods Ass'n v. Amestoy, 92 F.3d 67, 70 (2d Cir. 1996) ("because the injunction at issue stays 'government action taken in the public interest pursuant to a statutory . . . scheme,' this Court has determined that the movant must satisfy the more rigorous 'likelihood of success prong") (quoting Able v. United States, 44 F.3d 128, 131-32 (2d Cir. 1995)).

When a preliminary injunction is sought to prevent infringement of First Amendment rights, irreparable harm is presumed. See Green Party of New York State, 389 F.3d at 418; International Dairy Foods Ass'n, 92 F.3d at 71 ("It is established that '[t]he loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury.") (citation omitted).

A. NYSRA Is Likely To Succeed On The Merits Of Its First Amendment Claim

1. Regulation 81.50 Impermissibly Compels Speech

The First Amendment guarantees "both the right to speak freely and the right to refrain from speaking at all." Wooley v. Maynard, 430 U. S. 705, 714 (1977). It applies to compelled speech as it does to restraints on speech. See id. This is because the right to refrain from speaking "serves the same ultimate end as freedom of speech in its affirmative aspect." Pacific Gas & Elec. Co. v. Public Utilities Comm'n of California, 475 U.S. 1, 11 (1986) (internal

quotations omitted). Compelled speech, like bans on speech, violate "the fundamental rule of protection under the First Amendment," namely "that a speaker has the autonomy to choose the content of his own message." Hurley v. Irish-American Gay, Lesbian and Bisexual Group of Boston, 515 U.S. 557, 573 (1995). State regulations compelling speech must be carefully scrutinized because "unjustified or unduly burdensome disclosure requirements might offend the First Amendment by chilling protected commercial speech." Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio, 471 U.S. 626, 651 (1985).

Thus, the Supreme Court has repeatedly struck down laws that compel a speaker to utter a message dictated by the government. The Court first invalidated an outright compulsion of speech in West Virginia Board of Education v. Barnette, 319 U. S. 624 (1943). The State required every schoolchild to recite the Pledge of Allegiance while saluting the American flag. The Court held that the First Amendment does not "lefave] it open to public authorities to compel [a person] to utter" speech with which he does not agree. Id. at 634. In Wooley v. Maynard, 430 U. S. 705 (1977), the Court struck down a statute requiring automobile license plates to bear the State's motto, "Live Free or Die." The Court explained that requiring citizens to "use their private property as a 'mobile billboard' for the State's ideological message" violated the First Amendment by compelling speech. Id. at 715. In Pacific Gas & Electric Co., the Court invalidated a state order requiring a utility company to include in its billing envelopes messages prepared by a consumer organization. The Court reasoned that, because corporations, like individuals, have "the choice of what not to say," the order violated the First Amendment by forcing the company "to associate with speech with which [it] may disagree." Pacific Gas & Electric Co., 475 U.S. at 15-16. And in Hurley, the Court reversed a Massachusetts ruling requiring the (private) organizers of Boston's St. Patrick's Day Parade to include a group of

marchers who wished to convey a message which the promoters opposed, explaining that the state may not "compel affirmance of a belief with which the speaker disagrees." Hurley, 515 U.S. at 573-74 (citation omitted).

The right not to speak "applies not only to expressions of value, opinion, or endorsement, but equally to statements of fact the speaker would rather avoid." Hurley, 515 U.S. at 573-74 (citations omitted). In Riley v. National Federation of the Blind, 487 U.S. 781 (1988), the Court found that a state law requiring fundraisers to disclose the percentage of funds that were actually paid to charity before seeking contributions from prospective donors violated the First Amendment. The Court refused to distinguish Riley from other compelled speech cases such as Pacific Gas, Barnette, or Wooley, "simply because [these latter cases] involved compelled statements of opinion while here we deal with compelled statements of 'fact': either form of compulsion burdens protected speech." See Riley, 487 U.S. at 797-98.

This protection against compelled speech also extends to commercial speech. See United States v. United Foods, Inc., 533 U.S. 405, 410 (2001); Zauderer, 471 U.S. at 651 ("[U]njustified or unduly burdensome disclosure requirements might offend the First Amendment by chilling protected commercial speech."); International Dairy Foods Ass'n, 92 F.3d at 71 ("The right not to speak inheres in political and commercial speech alike.") (citations omitted).

Regulation 81.50 impermissibly compels speech. In requiring the posting of the caloric counts of food items on menu boards next to the price, the Regulation forces restaurants to use their most important tool for communicating with their customers to voice a point of view with which they disagree, namely that calories are the only nutritional criterion that patrons need toconsider when making food selections. These restaurants, which have voluntarily provided comprehensive nutritional information to the public, have spent time and resources in

understanding what nutritional information can best serve their consumers. By forcing restaurants to post calories in isolation, restaurants are required to speak in a way that communicates the City's point of view regarding the significance of calories and undermines their own point of view. This approach is doubly offensive here, because menus and menu boards are among the most important ways that restaurants communicate with their customers. To permit the government to commandeer that valuable mode of communication and dictate the message that restaurants convey—a message they do not wish to convey—raises free speech concerns.

In *United Foods*, the Supreme Court held that a monetary assessment imposed on mushroom growers pursuant to a federal act to fund advertisements of mushrooms violated the First Amendment because it compelled the growers to subsidize commercial speech with which they disagreed. *United Foods*, 533 U.S. at 411-16. The government used the assessments to pay for generic advertising to promote the sale of mushrooms. *Id.* at 408. The plaintiff objected because it did not want to support a generic advertising campaign that promoted all mushrooms, but rather wanted to convey a message that its mushrooms were superior to mushrooms grown by other producers. *Id.* at 411. Notably, the Court drew a distinction between the (unconstitutional) statute before it, which "simply" required the mushroom growers to "support speech by others" by paying money, and even more onerous statutes, which force a party to "utter the speech itself." *See id.* at 413; *see also Johanns v. Livestock Marketing Ass'n*, 544 U.S. 550, 568 (2005) (Thomas, J. concurring) ("The government may not, consistent with the First Amendment, associate individuals or organizations involuntarily with speech by attributing an unwanted message to them. . . .").

The Regulation here is far more offensive than the one at issue in *United Foods*, for it requires a restaurant to use its own forum to convey the Department of Health's message as if it were the restaurant's message. Similarly, Regulation 81.50 compares unfavorably to the state law struck down in Wooley. There, the plaintiff disagreed with the content conveyed on a stateissued license plate. Here, the City demands that the content be conveyed not on a governmentissued license plate, but on the restaurant's own signage.

Of course, the government retains the power to compel disclosure needed to prevent misleading commercial speech. But the Regulation cannot be sustained on that basis, because it has nothing to do with protecting consumers from being misled.⁶ This Regulation is not actually

The Supreme Court's decision in Zauderer highlights the distinction between permissible and impermissible disclosure requirements. In Zauderer, the Court addressed a state rule concerning lawyers who advertised their contingency fee rates, requiring contingency fee advertisements to disclose whether clients would have to pay costs on top of the contingency fee. The Court upheld this disclosure requirement based on its finding that omission of this information could mislead consumers. See Zauderer, 471 U.S. at 648; see also United Foods, 533 U.S. at 416 (finding Zauderer inapplicable because there was no suggestion "that the mandatory assessments [at issue in United Foods] . . . [were] somehow necessary to make voluntary advertisements nonmisleading for consumers."). Here, the compelled disclosure of calorie information is not needed to make menu boards non-misleading. Consumers are well aware that food has calories and would never think that the absence of calorie information indicates that the food does not have calories, or even that the food is low in calories. Indeed, the Department of Health does not claim that preventing consumers from being deceived or misled is the motivation behind the Regulation.

This case is also distinguishable from the Second Circuit's opinion in National Electric Manufacturers Association v. Sorrell, 272 F.3d 104 (2d Cir. 2001). In Sorrell, the court applied Zauderer's rational basis test to a state labeling law that required the disclosure of mercury content on certain commercial products. The court found that Zauderer's rational basis test was the proper test to apply because the statute at issue compelled only "purely factual and uncontroversial" disclosure of otherwise unknown safety information. Id. at 113-14 (quoting Zauderer, 471 U.S. at 651). Sorrell's analysis is irrelevant here because (a) the fact that food contains calories is already well known and the amount of calories in any given food item is disclosed elsewhere, and (b) the compelled speech at issue is not "purely factual and uncontroversial," but rather forces restaurants to use their most valuable communication tool to convey a viewpoint with which they disagree. In addition, Sorrell includes dicta that might be deemed overly expansive in the light of the Supreme Court's 2001 decision in United Foods, which clarified that Zauderer does not apply when restrictions on speech are not intended to prevent consumers from being misled. United Foods, 533 U.S. at 416. United Foods was decided only a few weeks before Sorrell but Sorrell did not address the new Supreme Court case.

a "disclosure" requirement. It does not require restaurants to disclose information about calories or anything else. It applies only to restaurants that already provide calorie information. It thus makes the voluntary disclosure of information more onerous than it would otherwise be. The Regulation thus chills disclosure. In fact, some restaurants have found the burdens imposed by the regulation to be so onerous as to cause them to withdraw nutrition information rather than comply with the Regulation. See Riley, 487 U.S. at 794 (regulation "necessarily chill[ed] speech" in violation of First Amendment by subjecting speakers to threat of litigation, thus "reduc[ing] the quantity of expression" (citation omitted).

Members of NYSRA that wish to provide caloric information want to do so in context. They do not wish to isolate caloric information and highlight it to the exclusion of other nutrition information. In contrast, the City demands the right to commandeer the menu and to force the owner of the menu to convey information that the owner does not want to convey on the menu. Some restaurants have already withdrawn their disclosures rather than comply with the Regulation. The First Amendment prohibits this state action.

2. Regulation 81.50 Impermissibly Burdens Protected Speech, **Even When Evaluated Under Intermediate Scrutiny**

In United Foods, discussed supra, the Court found that because compelled speech is such a serious government intrusion, it did not need to apply the four-part test set out in Central Hudson. As noted above, this is an a fortiori case from United Foods because it involves compelled speech itself, rather than the subsidy at issue there.⁷

In United Foods, the Court went further and suggested that it might be time to rethink Central Hudson. The Court noted that many of its members had criticized Central Hudson in other cases; but whether to overturn Central Hudson was a question left to a later case. The Court later granted certiorari to consider that very question, but procedural issues persuaded a majority of the Court not to reach the merits of that case. See Nike, Inc. v. Kasky, 539 U.S. 654, 665 (2003) (Stevens, J., concurring in dismissal of *certiorari*).

Nevertheless, even if this Court were to apply the test of Central Hudson, Regulation 81.50 should be held unconstitutional. In *Central Hudson*, the Supreme Court articulated a fourpart analysis for determining whether a government restriction on commercial speech violates the First Amendment. Under this test, a court must determine: (1) whether the expression concerns lawful activity and is not misleading; (2) whether the asserted governmental interest is substantial; (3) whether the Regulation directly advances the asserted interest and (4) whether it is not more extensive than is necessary to serve that interest. Central Hudson, 447 U.S. 557, 566 (1980).

- 1. The City makes no contention that the speech at issue is misleading or concerns unlawful activity. The speech plainly falls within the protection of the First Amendment.
- 2. The state has a substantial interest in public health. The Department of Health promulgated the Regulation to "decrease [individuals'] risk for the negative health effects of overweight [sic] and obesity associated with excessive calorie intake." Notice of Adoption of An Amendment (81.50) to Article 81 of the New York City Health Code (Dec. 5, 2006) ("Notice of Adoption") at I (copy attached at Appendix Tab L). NYSRA agrees that the government's interest in protecting human health by reducing obesity is substantial. This is the interest that the Department of Health proffered in the Notice of Adoption. And it is the interest that the Regulation must be shown to further.8

The Department of Health may seek to justify the Regulation simply as a means to better inform a certain group of restaurant-goers (i.e., those that eat at the estimated ten percent of the restaurants covered by the Regulation) about calories. But such a goal-divorced from the goal of reducing obesity—is not a legitimate basis on which to sustain the compelled speech at issue here. As the Second Circuit has already ruled, "consumer curiosity alone is not a strong enough state interest to sustain compulsion of even an accurate, factual statement . . . in a commercial context." See International Dairy Foods Ass'n, 92 F.3d at 74 (citation omitted).

3. The City cannot demonstrate that the Regulation "advances [the City's] interests in a direct and material way." Edenfield v. Fane, 507 U.S. 761, 767 (1993); Central Hudson, 447 U.S. at 564. The burden of justifying a restriction on commercial speech rests with the proponent of the restriction. See Edenfield, 507 U.S. at 770. "[M]ere speculation or conjecture" will not suffice to sustain this burden. Id. Rather, the Department "must demonstrate that the harms it recites are real and its restriction will in fact alleviate them to a material degree." Id. at 771. Otherwise, "a State could with ease restrict commercial speech in the service of other objectives that could not themselves justify a burden on commercial expression." Rubin v. Coors Brewing Co., 514 U.S. 476, 487 (1995) (quoting Edenfield, 507 U.S. at 771); accord Greater New Orleans Broad. Ass'n v. United States, 527 U.S. 173, 189 (1999).

The studies upon which the Department of Health relied in promulgating the Regulation do not conclude that posting calorie information in isolation on menu boards will have the effect of decreasing caloric intake and the incidence of obesity. The Department of Health cites to three studies, all of which are authored by the same two lead authors. See Notice of Adoption at 2 nn. 14-18. The Court need not consider whatever defects these studies might have because the authors themselves do not claim for their studies the propositions for which the Board of Health proffered them. In the most recent of the cited papers, the authors specifically limit their claims to the "potential" health benefits. The authors never put forth a correlation between posting nutritional information and observable health effects, let alone an impact on obesity rates. The authors state that "[p]rovision of nutrition information on restaurant menus could potentially have a positive impact on public health by reducing the consumption of less-healthful foods." Scot Burton, Ph.D., et al., Attacking the Obesity Epidemic: The Potential Health Benefits of Providing Nutrition Information in Restaurants, 96 Am. J. of Pub. Health 1669 (2006) (emphasis added). The authors do no more than suggest that "new restaurant-oriented nutrition information initiatives may be warranted." Id. at 1674 (emphasis added). Additionally, the article does not advocate providing calorie information in isolation. In fact, the authors opine that calories displayed with other nutrient information (i.e., fat, saturated/trans fats and sodium levels) could have a greater impact on purchase intentions than calories alone. See id.9

Moreover, the Department of Health cannot demonstrate a causal link between the requirements of Regulation 81.50 and the reduction of obesity "to a material degree." Bad Frog Brewery, Inc. v. New York State Liquor Auth., 134 F.3d 87, 98 (2d Cir. 1998) (quoting Edenfield, 507 U.S. at 771) (emphasis in original). Only ten per cent of the City's restaurants will be required to post calorie information on their menus and menu boards. The Department of Health offers no information as to how many City residents take all (or even a substantial portion) of their meals in chain restaurants, how those customers might be affected by calorie information on menu boards, or what the Department of Health did to confirm the effectiveness of its regulation. In addition, the Regulation exempts many of the foods offered by restaurants by requiring that calorie count information be provided only for foods listed on the menu board. Finally, the Department of Health has not accounted for the fact that the Regulation actually causes some restaurants to cease providing nutrition information. The Department of Health simply denied that this would happen. 10

The study found that purchase intentions for a chef salad did not substantially change when subjects were given only calorie information, but that purchase intentions for a chef salad were substantially lower when subjects were given calories plus nutrient information. The authors concluded that this was due to the fact that the salad, while containing a moderate amount of calories, "substantially exceeds the levels of fat and saturated fat expected by consumers." Attacking the Obesity Epidemic, 96 Am. J. of Pub. Health at 1673-74.

See New York City Department of Health and Mental Hygiene, Summary and Response to Public Hearing and Comments Received Regarding Amendment of Article 81 of the New York City Health Code Adding a New Section 81.50 to Require Labeling on Menus and Menu Boards, Footnote continued on next page

In fact, the Department of Health acknowledged that it had no idea whether Section 81.50 would have any affect on health, let alone a material one. In response to one of the public comments that it received, questioning whether the Regulation would achieve its stated goal, the Department of Heath acknowledged that "[t]he health impact of calorie labeling will be evaluated" and that it is just one of the policy efforts that the city is pursuing. See Summary and Response to Public Hearing and Comments Received Regarding Amendment of Article 81 of the New York City Health Code Adding a New Section 81.50 to Require Calorie Labeling on Menus and Menu Boards, at 4 (Nov. 27, 2006) (emphasis added) (Appendix Tab G). A Department representative made similar comments to The New York Times. See Ray Rivera, Survey Swaps MetroCards for Meal Receipts, N.Y. Times, March 30, 2007, at B2 ("Because we are breaking new ground with this initiative, it is crucial that we evaluate our efforts so we can assess their impact and help combat obesity in New York City and the nation.") (copy attached at Appendix Tab M). Without any evidence that the Regulation will have a positive impact on the health of its citizens, the Regulation cannot withstand First Amendment scrutiny. See Rubin, 514 U.S. at 490 (striking down federal law prohibiting the disclosure of alcohol content on beer labels because the government failed to provide any "convincing evidence" that the Regulation would in fact further the government's asserted interest). The Department of Health cannot fall back on its assertion that the Regulation is justified by the fact that consumers would like to have access to this information, as it asserts in its Notice of Adoption. See Notice of Adoption at 3. The City

Footnote continued from previous page

at 5-6 ("It would be a striking development if establishments which had already made nutrition information publicly available withdrew this information rather than making it available where consumers would readily see it.") (Appendix Tab G).

cannot meet its burden by merely claiming strong consumer interest or even the public's right to know. See International Dairy Foods Ass'n, 92 F.3d at 74.

4. Regulation 81.50 also fails because "the speech restriction" may not be "more extensive than necessary to serve the interests that support it." Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 556 (2001) (internal quotations omitted). The law demands "a means narrowly tailored to achieve the desired objective." Id. (internal quotations omitted); Bad Frog Brewery, Inc., 134 F.3d at 100-01 ("Central Hudson's fourth criterion . . . requires consideration of whether the prohibition is more extensive than necessary to serve the asserted state interest.") (citations omitted). A restriction on speech is "more extensive than necessary" if "less intrusive" alternatives are available. Rubin, 514 U.S. at 491; Bad Frog Brewery, 134 F.3d at 101.

Here, the City has spurned the many alternatives to the Regulation's requirement to post calorie information on menus and menus boards. Even accepting, arguendo, the City's premise that providing calorie information at the point of purchase is useful in combating obesity, less burdensome alternatives are available. These include providing comprehensive nutritional information (including calories) on (i) countermats, (ii) tray liners; (iii) brochures placed by cash registers; or (iv) on separate billboards, posters, or stanchions. Additionally, in order to ensure that consumers know that nutritional information is readily available, menu boards could contain a message directing consumers to other sources of information. These alternatives would give consumers similar access to calorie information in a manner less likely to be offensive to restaurants. In fact, several restaurants proposed such alternatives to the Department, but the Department rejected them,

CONCLUSION

For all the reasons stated above, the Court should grant plaintiff's motion for declaratory relief on its preemption claim and for preliminary injunctive relief on its First Amendment claim.

Dated: June 14, 2007

New York, New York

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Exhibit B

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UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

New York State Restaurant Association,

Plaintiff,

No. 07 Civ. 5710 (RJH)

v.

NEW YORK CITY BOARD OF HEALTH, ET AL.,

Defendants.

REPLY MEMORANDUM IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION, DECLARATORY RELIEF AND PARTIAL SUMMARY JUDGMENT

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I. THE NATIONAL LABELING AND EDUCATION ACT PREEMPTS REGULATION 81.50

The City and its *amici* begin their discussions of express preemption by discussing a provision that does not apply to the case and that Plaintiff has not claimed applies to this case—21 U.S.C. § 343-1(a)(4). When the City does discuss the applicable provision, section 343-1(a)(5), it argues that the provision does not apply here because the posting of calorie content by restaurants is not a nutrition content "claim" covered by regulations promulgated under section 343(r) and thus does not fall within subsection (r)'s corresponding preemption provision. According to the City and amici, posting calorie information is not a nutrition content "claim" because such posting does not "characterize" the level of the nutrient (i.e., calories). At the same time, the City admits that posting the calorie content would be covered by section 343(r) if the restaurant used "descriptive words, such as 'contains." Def. Br. 9 n.11. Under this reading of the statute, a restaurant that claimed on its menu that a certain food item "contains" 100 calories (when it in fact contained 500 calories) would be covered by section 343(r), and the restaurant would have misbranded its product under the NLEA. But, according to the City and its amici, the same restaurant could evade coverage of section 343(r) and the FDA's regulations by removing the word "contains" and listing the same "100 calories" next to the name of the same food item. That is not what the statute and regulations say.

We respectfully urge the Court to reject these strained arguments. The statute requiring preemption is clear. Through its regulations (which warrant deference under Chevron, U.S.A. v. Natural Resources Defense Council, 467 U.S. 837 (1984)), and its explanations of those regulations, the FDA has also made it clear that a statement such as

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"100 calories" is a permissible "nutrient content claim" as long as it is not false or misleading.

A. The Statutory and Regulatory Scheme

As demonstrated in Plaintiff's opening brief at pages 8 to 18, Regulation 81.50 is barred by the express preemption provision of the National Labeling and Education Act of 1990 ("NLEA"). Subsection (r) imposes restrictions on the ability of "food purveyors," including restaurants, to make affirmative nutrition and health claims about food. See Public Citizen, Inc. v. Shalala, 932 F. Supp. 13, 15 (D.D.C. 1996). The statute's express preemption provision provides that "no State . . . may directly or indirectly establish ... any requirement respecting any claim of the type described in section 343(r)(1) of this title [i.e., nutrition content claims] made in the label or labeling of food [that] is not identical to the requirement of section 343(r) of this title [except claims which are explicitly exempted by section 343(r) itself—claims about cholesterol. saturated fat, dietary fiber and nutrients that can cause disease]." 21 U.S.C. § 343-1(a)(5). The NLEA expressly completely preempts state law that differs in any way from the requirements under section 343(r). Congress delegated the implementation of the NLEA to the FDA, which promulgated final regulations for nutrition and health claims for restaurant foods. The regulations provide that the same definitional standards apply to restaurant foods as to other foods with respect to making a nutrition claim. However, the FDA's regulations give restaurants flexibility in determining how they comply with

¹ The NLEA, Pub. L. No. 101-535, 106 Stat. 4501, added new subsections 403(q) and (r) and 403A to the Federal Food, Drug and Cosmetic Act ("FDCA"). Some of the relevant provisions of the NLEA are codified at 21 U.S.C. §§ 343(r) and 343-1(a)(5), and others are not codified, but are set out as a note following 21 U.S.C.A. § 343(r).

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the nutrition labeling requirements in order to encourage restaurants voluntarily to provide nutrition information. *See* 61 Fed. Reg. 40320, 40320 (Aug. 2, 1996).

Thus, the relevant statutes for restaurants—and for evaluating Regulation 81.50, which seeks to require some restaurants to post calorie information on their menus and menu boards—are 21 U.S.C. §§ 343(r) and 343-1(a)(5). However, before analyzing those statutes, it is useful to address section 343(q) briefly. Subsection (q) governs mandatory nutrition labels for packaged foods. Restaurants are completely exempt from compliance with subsection (q). 21 U.S.C. § 343(q)(5)(A) ("Subparagraphs (1), (2), (3), and (4) shall not apply to food—(i) which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments "). Congress exempted restaurants from subsection (q) because "full labeling [was] impractical." See H.R. Rep. No. 101-538 at 7 (1990), reprinted in 1990 U.S.C.C.A.N. 3336, 3337. Subsection (q)'s preemption clause is 21 U.S.C. § 343-1(a)(4). Courts have held that subsection (q) does not preempt state law concerning restaurants because restaurants are exempt from subsection (q) and thus equally exempt from its preemption section, 21 U.S.C. § 343-1(a)(4), by the statute's express terms. See Pelman v. McDonald's Corp., 237 F. Supp. 2d 512, 526 (S.D.N.Y. 2003); but see Cohen v. McDonald's Corp., 347 Ill. App. 3d 627, 808 N.E.2d 1 (Ill. App.

² The thrust of *amicus* Public Citizen's brief is that restaurants are exempt under section 343(q), and therefore, state law governing them is not preempted. The argument has no relevance to this case because Plaintiff's member restaurants are claiming preemption under sections 343(r) and 343-1(a)(5), not sections 343(q) and 343-1(a)(4). Unlike subsection (q), subsection (r) does not exempt restaurants. *See Public Citizen, Inc. v. Shalala,* 932 F. Supp. 13, 15 (D.D.C. 1996). Public Citizen's discussion (Br. 14-16) of the legislative history of subsection (q) should not distract the Court from the real issue in this case, which is the scope of subsection (r)'s preemption provision.

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1 Dist. 2004) (state law claims preempted under § 343-1(a)(4)).³

In contrast to subsection (q), which requires nutrition information panels on packaged food, subsection (r) governs the much broader category of nutrition claims and health claims in all "labels and labeling" of food. And, in contrast to the complete exemption for restaurants in subsection (q), restaurant foods have only a limited exemption under subsection (r) for four items: cholesterol, saturated fat, dietary fiber and nutrients that can cause disease. *Compare* 21 U.S.C. § 343(q)(5)(A)(i) with § 343(r)(5)(B). Outside the four specified exemptions, restaurants are subject to subsection (r).

Subsection (r) provides that if a "claim is made in the label or labeling of the food which expressly or by implication characterizes the level of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of food," the claim must be in compliance with regulations promulgated by the FDA. 21 U.S.C. § 343(r)(1)(A), (r)(2)(A)(i). And because restaurants are subject to subsection (r), the corresponding preemption provision in section 343-1(a)(5) applies to restaurants and forbids state regulation that is "not identical to" FDA regulations, except for regulations governing cholesterol, saturated fat, dietary fiber and nutrients that can cause disease.

The FDA has exercised authority delegated by Congress in the NLEA to promulgate labeling requirements applicable to restaurants that disclose nutrition information, and has purposefully given restaurants wide flexibility in the manner in

³ Public Citizen criticizes Plaintiff for not citing *Pelman* in its opening brief, but *Pelman* addressed subsection (q) and subsection (q)'s preemption provision. In fact, the only case that addresses preemption under subsection (r)—the claim at issue here—is *Reyes* v. *McDonald's Corporation*, 2006 WL 3253579 (N.D. Ill. Nov. 6, 2006). Plaintiff relied on *Reyes* in its opening brief, but the City and the *amici* ignore it. *See infra* pp. 18-19.

which they do it. 21 CFR § 101.10. Subsection (r) requires regulations governing any "claim" "made in the label or labeling of the food which expressly or by implication characterizes the level of any nutrient." See 21 U.S.C. § 343(r)(2)(A)(i). The FDA's regulations provide that, if a restaurant makes "a claim . . . which expressly or implicitly characterizes the level of any nutrient," it must do so in accordance with FDA regulations (except of course the regulations that apply to the four exempt categories, irrelevant here). Consistent with this regime, the FDA's regulations cover restaurants that make claims about their nutritional information:

The following foods are exempt from this section or are subject to special labeling requirements . . . (2) Food products which are: (i) served in restaurants, provided, that the food bears no nutrition claims or other nutrition information in any context on the label or in labeling or advertising. Claims or other nutrition information subject the food to the provisions of this section.

21 CFR § 101.9(j) (emphasis in original); see 21 CFR § 101.13(n) ("Nutrition labeling in accordance with § 101.9, § 101.10, or § 101.36, as applicable, shall be provided for any food for which a nutrient claim is made."). Because restaurants that do make "claims" are "subject... to" the NLEA and FDA's regulations, 21 U.S.C. § 343-1(a)(5) preempts inconsistent state law.

B. A Statement By A Restaurant About The Amount Of Calories In Food Is A "Claim" that "Expressly Or By Implication Characterizes The Level Of Any Nutrient" Within the Meaning of Subsection (r)

The City's core argument (and that of *amicus* Public Citizen) is that a statement of a calorie amount—"100 calories"—is not a "claim" that "expressly or by implication characterizes the level of any nutrient" within the meaning of subsection (r) and regulations promulgated thereunder. Def. Br. 8-9; Pub. Cit. Br. 6-8, 16-25.

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1.

The Statute Is Unambiguous In Governing Express Claims of the Amount of Calories in Food

Evaluation of this contention must begin with the words of the statute. Section 343(r) declares food to be "misbranded" if it bears a "claim . . . made in the label or labeling of food which expressly or by implication . . . characterizes the level of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of food," unless "the characterization of the level made in the claim uses terms which are defined in regulations of the Secretary." 21 U.S.C. §§ 343(r)(1)(A), (r)(2)(A)(i). Subsection (q)(1), incorporated for this special purpose by subsection (r)(1)(A), requires disclosure of "the total number of calories." 21 U.S.C. § 343(q)(1)(C).

Subsection (r) thus covers any "claim" that "expressly characterizes" "the level of any nutrient" in the labeling of food, and includes "the total number of calories" as one such nutrient. If a statement "100 calories" does not "expressly characterize" the "total number of calories," it is hard to know what would. The City and Public Citizen, however, argue that "characterizations" cannot be quantitative ("100 calories"), but can only be qualitative. The statute itself forecloses that argument, for two reasons in addition to the plain language of subsection (r)(1)(A) itself.

First, the NLEA contains a provision with a delegation of authority relevant here. (This provision is not codified in Title 21 but can be found in the Notes after 21 U.S.C.A. § 343(r).) Section 3(b)(1)(A)(iv) of the NLEA provides that the Secretary "shall issue proposed regulations to implement section 403(r) of the ... Act [21 U.S.C. § 343(r)]... [and that] [s]uch regulations shall permit statements describing the amount and percentage of nutrients in food which are not misleading and are consistent with the terms defined in section 403(r)(1)(A)(i) of such Act [21 U.S.C. § 343(r)(1)(A)(i)]." Nutrition

Labeling and Education Act of 1990, Pub. L. No. 101-535, § 3(b)(1)(A)(iv), 106 Stat. 4501 (set out in Historical and Statutory Notes after 21 U.S.C.A. § 343(r)) (emphasis added). Here, the NLEA itself is directing that the Secretary promulgate regulations under subsection (r) concerning the amount of nutrients. Thus, statements describing the "amount" of nutrients in food are covered by 21 U.S.C. § 343(r)(1)(A)(i). Surely a statement "100 calories" is a statement "describing the amount" of total calories.

Second, section 343(r)(1) provides that nutrition fact statements required by subsection (q) on food labels (including the total calories) are not claims subject to subsection (r) when they are presented in the nutrition fact panel. 21 U.S.C. § 343(r)(1)(B) ("A statement of the type required by paragraph (q) of this section that appears as part of the nutrition information required or permitted by such paragraph [(q)—that is, on nutrition fact panels] is not a claim which is subject to this paragraph [subsection (r)]....") (emphasis added). Thus, if the statement 100 calories "appears as part" of the nutrition fact panel required by subsection (q), it is not a "claim" within the meaning of subsection (r)(1). By carving out statements that "appear as part" of the nutrition panel, the statute confirms that when the very same statements appear elsewhere on label or labeling—i.e., in locations not required by subsection (q)—then they do constitute "claims." The FDA's regulations, promulgated after notice and comment, codify this understanding of the statute:

Information that is required or permitted by § 101.9 [mandatory nutrition labeling requirements for food] or § 101.36 [mandatory labeling requirements for dietary supplements], as applicable, to be declared in nutrition labeling, and that appears as part of the nutrition label, is not a nutrient content claim and is not subject to the requirements of this section. *If such information is*

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declared elsewhere in the label or in labeling, it is a nutrient content claim and is subject to the requirements for nutrient content claims.

21 CFR § 101.13(c) (emphasis added); accord H.R. Rep. No. 101-538 at 19 (1990), 1990 U.S.C.C.A.N. at 3349 ("Section 403(r)(1)... removes the statements as to the amounts of nutrients required by section 403(q) from the disclosure and other requirements of section 403(r). However, section 403(r) would apply to any statement that is not required by section 403(q), including a statement identical to that on the nutrition label which appears on the front panel of the product.") (emphasis added). The FDA explained the significance of this statutory provision as follows in its notice of final rulemaking (for the rule that became 21 CFR § 101.13(c) quoted above):

The act specifically excludes statements that appear as part of nutrition information from the coverage of section 403(r)(1) of the act. This exclusion was included in the 1990 amendments to make it clear that the information required on the nutrition label, and the optional statements that are permitted as part of nutrition labeling, are not claims under section 403(r)(1) of the act and are not subject to the disclosure requirements in section 403(r)(2) of the act. (Congressional Record H5841 (July 30, 1990)). However, the legislative history of this provision specifically states that the identical information will be subject to the descriptor requirements [in §343(r)(2)(A)] if it is included in a statement in another portion of the label. (Id.). Consequently, FDA is proposing in § 101.13(c) that information that is required or permitted by § 101.9 to be declared in nutrition labeling, and that appears as part of the nutrition label, is not a nutrient content claim and is not subject to the requirements of this section. Proposed § 101.13(c) also states, however, that if such information is declared elsewhere on the label or in labeling, it is a nutrient content claim and is subject to the requirements for nutrient content claims.

56 Fed. Reg. 60421, 60424 (Nov. 27, 1991) (emphasis added).

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the Claim "100 Calories"

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2. The FDA's Regulations Are Unambiguous In Governing Express Claims of the Amount of Calories in Food—Including

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The FDA regulations implementing the NLEA provide that nutrient content claims may be expressed as numbers or values—in other words, that a quantitative statement is a "claim" that "expressly characterizes" "the level of any nutrient" in the labeling of food within the meaning of subsection (r). Those regulations, promulgated after a notice-and-comment process, are entitled to "controlling weight," see United States v. Haggar Apparel Co., 526 U.S. 380, 390, 392 (1999), and "are binding in the courts unless procedurally defective, arbitrary or capricious in substance, or manifestly contrary to the statute." See United States v. Mead Corp., 533 U.S. 218, 227 (2001) (footnote omitted).

Most prominently, 21 C.F.R. § 101.13(c), discussed above, addresses information required to be printed in a nutrition facts panel, such as "total calories," and states that "[i]f such information is declared elsewhere in the label or in labeling, it is a nutrient content claim and is subject to the requirements for nutrient content claims." 21 CFR § 101.13(c). See also FDA, Food Labeling: Questions and Answers, Volume II, "A Guide for Restaurants and Other Retail Establishments" (hereinafter "FDA Q&A Vol. II"), Question/Answer Number 76 (advising restaurants that providing nutritional information subjects the restaurant to the requirements of the NLEA) (available at http://www.cfsan.fda.gov/~frf/qatext2.html (last visited July 18, 2007).

In addition, at least two provisions of the FDA regulations (21 CFR §§ 101.13(b)(1) and 101.13(i)(3)) explained in this and the next paragraph define "nutrient content claims" in terms of the *amount* of the nutrient value. To understand the

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significance of these definitions, one must first appreciate that the regulations—like the NLEA itself—cover both "expressed" and "implied" nutrient content claims. An "implied" nutrient content claim—which is not involved in this case—is defined by reference to certain "descriptor" words such as "healthy," see 21 CFR § 101.13(b)(2).

And here is how the FDA defines "expressed" nutrient content claims which is what this case is about: "An expressed nutrient content claim is *any direct statement about the level* (or range) of a nutrient in the food, e.g., 'low sodium' or 'contains 100 calories." 21 CFR § 101.13(b)(1) (emphasis added).

The regulations go on to set forth the requirements for both "expressed" and "implied" nutrient content claims and specifically for when a claim "may contain a statement about the amount or percentage of a nutrient." 21 CFR § 101.13(i). An implied nutrient content claim is allowed if the statement meets certain definitional requirements contained in "Subpart D" [§ 101.13(i)(1)], or if it fails to meet the definitional requirements in Subpart D but the label contains a disclaimer [§ 101.13(i)(2)]. In contrast, an expressed nutrient content claim is allowed irrespective of Subpart D, so long as "[t]he statement does not in any way implicitly characterize the level of the nutrient in the food and it is not false or misleading in any respect (e.g., '100 calories' or '5 grams of fat'), in which case no disclaimer is required." 21 CFR § 101.13(i)(3) (emphasis added).

[Footnote continued on next page]

⁴ According to the City and Public Citizen, 21 CFR § 101.60 excludes statements such as "100 calories" from the "defin[ition of] nutrient content claims for the calorie content of foods." Pub. Cit. Br. 24; see Def. Br. 9 n.12. However, § 101.60 does not define "nutrient content claims." That definition is quoted above. See supra pp. 9, 10 (quoting §§ 101.13(b)(1), 101.13(c)). Rather, § 101.60 is a component of "Subpart D," which treats certain implied claims and which is limited by § 101.13(i). Under § 101.13(i), nutrient content claims are permitted if they comply with a relevant section within "Subpart D"

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Thus, section 101.13 of the FDA's regulations provides specifically that total calories is a "claim" if it appears anywhere besides the nutrition facts panel, and that "100 calories" is a permissible expressed nutrient content claim—in the words of the statute, a "claim" that "expressly characterizes" "the level of any nutrient" in the labeling of food. This regulation is of "controlling weight." *See Haggar Apparel Co.*, 526 U.S. at 392.

In its final rulemaking statement adopting the regulations under the NLEA upon which we rely above, following the notice and comment period, the FDA specifically rejected the argument now urged by the City and amicus Public Citizen. The FDA had been asked to exclude statements about "simple factual information" from the definition of "nutrient content claim" on the theory that such a statement is not "a claim that 'characterizes' the level of any nutrient" within the meaning of the statute. But the FDA rejected that contention, embraced the view that a quantitative factual "statement" about the amount of a nutrient is a "claim" that "characterizes the level" of the nutrient within the meaning of the statute, and promulgated final and binding regulations to that effect.

And the FDA rejected this contention for some of the same reasons we have urged above:

One comment stated that the claims that are subject to the proposed regulations, which implement section 403(r)(1)(A) of the act [21 U.S.C. § 343(r)(1)(A)], are appropriately called "nutrient descriptors," not "nutrient content" claims as proposed by FDA. The comment pointed out that the statutory language of the 1990 amendments does not include the phrase "nutrient content" claim. It stated that the words in section 403(r)(1)(A) of the act refer

[[]Footnote continued from previous page]

^{(§ 101.13(}i)(1)), or if they do not comply with "Subpart D" but contain a disclaimer (id. § 101.13(i)(2)), or if they do not comport with Subpart D but make no implied claim (id. § 101.13(i)(3). Since "100 calories" falls under § 101.13(i)(3), in order to be permissible, it need not comport with § 101.60 or anything else in Subpart D, and § 101.60 simply does not shed any light on whether "100 calories" is or is not a "claim."

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to a covered claim as a claim that "characterizes the level of any nutrient * * *." The comment's purpose in contrasting the wording of the proposal and that of the statute is to limit the applicability of the regulation to claims about the level of a nutrient and to exclude statements about amounts of nutrients. The comment stated that simple factual information about the nutrient content of a food, for which no characterizing claims are made, is explicitly excluded from regulation under section 403(r)(1)(A) of the act. It said that the last sentence in section 403(r)(1) of the act provides that a statement of the type contained in nutrition labeling—for example, that a food contains 25 calories per serving, or 10 percent of the U.S. Recommended Daily Allowance (U.S. RDA) for vitamin C, or 50 milligrams (mg) of sodium—is not a claim characterizing the level of the nutrient. The comment requested that to assure that the regulations for section 403(r)(1)(A) of the act claims are not misunderstood to extend to nutrient statements that do not "characterize the level of a nutrient," all references to "nutrient content" claims be redesignated to "nutrient descriptors" or "nutrient descriptor claims."

The agency advises that while it can agree that the terms "nutrient descriptor" and "nutrient descriptor claims" may be used to describe the claims subject to section 403(r)(1)(A) of the act and these regulations, it does not agree that the scope of the statute and the regulations excludes statements of the amount of a nutrient in a food. The [distinction] the comment draws between "nutrient descriptors" and "nutrient content" claims is unpersuasive. In fact, one of the sponsors of the 1990 amendments in the Senate specifically used the term "nutrition content claim" to refer to claims covered under section 403(r)(1)(A) (136 Cong. Rec. S16608 (October 24, 1990)). Moreover, the statement in section 403(r)(1) of the act referred to by the comment as excluding from coverage statements of the type contained in nutrition labeling, in fact excludes "a statement of the type required by paragraph (q) that appears as part of the nutrition information required or permitted by such paragraph * * *." FDA stated in the general principles proposal (56 FR 60421 at 60424), that the legislative history of this provision specifically states that the identical information /i.e., the identical information that would be required in the nutrition fact panel required by subsection (q) | will be subject to the descriptor requirements if it is included in a statement in another portion of the label (136 Congressional Record H5841

(July 30, 1990)). Furthermore, section 3(b)(1)(A)(iv) of the 1990 amendments provides that the mandated regulations "shall permit statements describing the amount and percentage of nutrients in food which * * * are consistent with the terms defined in section 403(r)(2)(A)(i) of such Act." Again, if statements of the amount and percentage of nutrients were not subject to section 403(r)(1)(A) of the act, there presumably would have been no need for Congress to express its desire that such claims be permitted by the regulations. Accordingly, FDA concludes that section 403(r)(1)(A) of the act and therefore these final regulations apply to statements of the amount of a nutrient in food as well as to statements of the level of a nutrient in food.

58 Fed. Reg. 2302, 2303-04 (Jan. 6, 1993) (emphasis added).

3. The City's Argument Leads To Irrational Results

As they must, the City and *amicus* Public Citizen acknowledge that the statement "contains 100 calories," is a nutrient content claim, *see* 21 CFR § 101.13(b), but they argue that the statement "100 calories" is not a nutrient content claim. Def. Br. 9-10; Pub. Cit. Br. 19-25. Plainly the two phrases mean the same thing. True, one uses the word "contains" and the other does not; but, in the context of nutrition amounts, what else could the statement "100 calories" mean, but that the food contains 100 calories?

Amicus Public Citizen further contends that the fact that the word "contains" is defined in the regulations is what makes the phrase a nutrient content claim. Pub. Cit. Br. 20-22. This argument has several flaws. First, the word "calories" is also defined in the regulations. 21 CFR § 101.9(c)(1).⁵ Second, the "definition" of "contains" on which Public Citizen relies is in section 101.54 (Pub. Cit. Br. 21), which is a component of

⁵ "Calories, total,' 'Total calories,' or 'Calories': A statement of the caloric content per serving, expressed to the nearest 5-calorie increment up to and including 50 calories, and 10-calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero."

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"Subpart D," not applicable to the type of "expressed" claim here at issue, see supra note

4. Compare 21 CFR §§ 101.13(i)(1) & (2) (governing claims that "implicitly characterize" the food) with § 101.13(i)(3) (governing claims that do not "in any way implicitly characterize" the food). Also, the definition of "contains" cited by the City and amicus is irrelevant for calories, because the definition concerns nutrients other than calories, see 21 CFR § 101.54 (applying "contains" requirements to nutrients listed in 21 CFR §§ 101.9(c)(8)(iv) and (c)(9), neither of which lists calories).

Finally, the City and the *amicus* offer no plausible explanation why the two phrases—"contains 100 calories" and "100 calories"—should be treated differently under the statute. If they were correct, a food purveyor would be misbranding its food under the regulations implementing section 343(r) for saying "contains 100 calories" when an item actually contained 300 calories, but would **not** be misbranding its food under those regulations for falsely saying "100 calories," instead of 300 calories. Under the City's

⁶ The City's reference to 58 Fed. Reg. 2302, 2310 ("[T]he statement 100 calories or 5 grams of fat on the principal display panel of a food would be a simple statement of amount that, by itself, conveys no implied characterization of the level of the nutrient.") is irrelevant because this case does not concern implied characterizations; it involves express characterizations. Def. Br. 9-10; Pub. Cit. Br. 21-22. Similarly, Public Citizen's reliance on no-action letters concerning *implicit* claims concerning "trans fat" and other matters are not germane. The issue here is "expressed claims" not "implicit claims." Pub. Cit. Br. 22-23. Finally, the City's and Public Citizen's reliance on the FDA September 2003 bulletin is unavailing because the excerpt they quote simply tracks the language of 21 CFR § 101.13(i), which, as discussed *supra* pp. 9-10, supports Plaintiff's position. Def. Br. 10; Pub. Cit. Br. 8, 22.

⁷ In a publication explaining how the NLEA applies specifically to restaurants, the FDA has explained that when the word "contains" is used with an amount of a nutrient, the **amount** is the characterization of the nutrient level, not the word "contains." See FDA Q&A Vol. II, No. 94 ("Furthermore, depending on the context in which it is used, the term 'contains' may itself be a nutrient content claim. A statement such as 'contains fiber' is a claim that a food is a 'good source' of fiber. (See attachment B). However, in a statement that includes a quantitative declaration, e.g., 'contains 2 grams of fiber,' the amount of fiber in the food is **characterized** by the quantitative declaration, '2 grams,' and the term 'contains' is a simple verb, not a nutrient content claim.") (emphasis added).

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theory, a restaurant could move in or out of the federal regulatory regime by adding or deleting the word "contains" before it disclosed "100 calories." The City does not explain how the two goals of the NLEA it identifies—"give consumers nutrition information about the products they are consuming and . . . prohibit misleading [nutrition] claims"—are met by making such a captious distinction. Def. Br. at 6.

C. Regulation 81.50 Is "Not Identical To" 21 CFR § 101.10 And Thus Is Preempted

The City acknowledges that if restaurants' statements regarding calories are "claims" "of the type described in section 343(r)(1)," then § 343-1(a)(5) preempts state law requirements "not identical to" the requirements of subsection (r), including regulations promulgated thereunder. Def. Br. 15-16; Pub. Cit. Br. 16-17.

To avoid preemption, the City argues that 21 CFR § 101.10, which grants restaurants flexibility on the manner in which they may present nutrient content claims, and the City's Regulation 81.50 are the same. That argument is wrong. The City's theory is that Regulation 81.50 "does not mandate restaurants to do anything different from what they are permitted to do" under 21 CFR § 101.10. Def. Br. 15. But 21 CFR § 101.10 permits restaurants to provide nutrition information in whatever "reasonable means" they choose, so long as the claims otherwise comport with applicable federal regulations. Regulation 81.50 is not identical to 21 CFR § 101.10. The City's regulation limits the choices of the restaurants, interferes with the flexibility granted to them by federal law, and commands them to present their claims in a specific way, whether they like it or not. Thus, Regulation 81.50 mandates that restaurants make a claim in a manner that is not required under 21 CFR § 101.10. Because the City's regulatory requirement is

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not identical to the requirements of 21 CFR § 101.10, the City's regulation is preempted. See Goya de Puerto Rico, Inc. v. Santiago, 59 F. Supp. 2d 274, 280 (D.P.R. 1999) (preempting state food labeling law mandating information where NLEA labeling regulations gave food manufacturers discretion).

In an attempt to avoid the plain meaning of "not identical to," the City says that Regulation 81.50 survives because the regulation is "not affirmatively different" from the requirements of 21 CFR § 101.10 and cites a passage from Volume 58 of the Federal Register. See Def. Br. 15 (citing 58 Fed. Reg. 2462, 2462). However the FDA was there using "affirmatively different" as another way of saying that preemption must be based on "substantive differences" between the local and federal regulations, not differences based on the mere use of different words. Thus, "affirmatively different" seems to require the same inquiry as "not identical to." See Bates v. Dow Agrosciences LLC, 544 U.S. 431, 454 (2005) (asking whether the two laws are "genuinely equivalent" and not different simply because they use different "phraseology") (emphasis in original). But even if "not identical to" did mean something other than "affirmatively different," the statutory language would govern.

In a footnote, the City argues that finding Regulation 81.50 preempted would mean that local governments would lose their "historic police power" "to regulate menus of restaurants within their border." Def. Br. 15 n.19. This assertion is meritless. Under the NLEA, local governments retain the authority to enforce FDA food labeling requirements. See 21 CFR § 100.2. The regulatory history cited by the City confirms that local governments may not do what the City is attempting to do here—to balkanize federal food labeling requirements. See 58 Fed. Reg. 2462, 2462 (noting that "one of the

goals of the [NLEA] is national uniformity in certain aspects of food labeling, so that the food industry can market its products efficiently in all 50 states in a cost-effective manner.") (citing to NLEA legislative history).

The City and Public Citizen argue that the Court must interpret the NLEA in a way that gives meaning to Congressional intent as stated in both subsections (q) and (r). Def. Br. 10; Pub. Cit. Br. 24-25. Plaintiff's reading does exactly that. And, contrary to the argument by the City and Public Citizen, Plaintiff's reading preserves a role for the states. Where (as here) a claim is "of a type" covered by subsection (r) and regulations promulgated thereunder, the states' rules are not displaced altogether. They are preempted only to the extent that they are "not identical to" federal requirements. (See also n.8.)

Thus, for example, ordinary state law would not be preempted as long as it imposed requirements "identical to" the requirements of the NLEA and implementing regulations. Consider, for example, a state tort action complaining that a restaurant had mis-stated the amount of calories posted in its nutrition labeling. As we have shown, such labeling must be in accordance with the FDA's regulations. For example, federal regulations would require the restaurant to employ the FDA's methodology for

⁸ Public Citizen argues that were Regulation 81.50 preempted, the role of local governments as "laboratories for experimentation" would be lost. Pub. Cit. Br. 12 n.8. Yet the NLEA provides a mechanism to allow for just this sort of experimentation. Under section 343-1(b), local governments may petition the FDA for an exemption from NLEA preemption. Section 343-1(b) balances local government's desire to promulgate non-uniform local law with the goal of achieving "national uniformity in certain aspects of food labeling, so that the food industry can market its products efficiently in all 50 states in a cost-effective manner." 58 Fed. Reg. 2462, 2462 (citation omitted). Thus, the FDA is empowered to permit local non-uniform laws that do not "unduly burden interstate commerce" and meet "a particular need for information which need is not met by the requirements of" the NLEA. 21 U.S.C. § 343-1(b)(2), (3).

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calculating calories. See 21 CFR § 101.10. Similarly, the level of the claimed caloric content would have be within 20% of the base. See 21 CFR § 101.9(g)(5). If the state tort action were premised on a claim that the restaurant violated standards of behavior "identical" to these federal requirements, then under the holding of Reyes, 2006 WL 3253579, at *7, the action would not be preempted. But if the tort action were based on standards of behavior "not identical to" the federal requirements, then the action would be preempted. Reyes is the only case we have found that decided the preemption issue presented here—a case not discussed by the City or its amici.

In *Reyes*, the court found plaintiffs' state-law claims imposing nutrition labeling requirements different from those of the NLEA and implementing FDA regulations to be preempted. *Id.* at *1. Plaintiffs filed suit for misrepresentation after McDonald's corrected the nutritional values of calories and fat published in its brochures and on its website. While McDonald's was exempt from subsection (q) of the NLEA, the court stated, it had voluntarily provided the nutrient information at issue, thereby losing its exemption from the FDA's regulations promulgated under subsection (r), but gaining protection from "not identical" state laws under the NLEA preemption provision applicable to subsection (r). *Id.* at *4. Applying the Supreme Court's preemption analysis in *Bates v. Dow Agrosciences LLC*, the *Reyes* court concluded that Plaintiffs' misrepresentation claims could proceed "only" to the extent that "[p]laintiffs seek to enforce . . . the requirements of the NLEA, and nothing further." *Id.* at *6.

D. The NLEA Authorized the FDA to Promulgate 21 CFR § 101.10

The City contends (Def. Br. 14-15) that section 101.10 is *ultra vires* because the FDA's authority was limited to "defining" the "terms" restaurants should use in making

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their nutrition claims. That argument is without merit. Section 343(r)(2)(A)(i) does not purport to limit the Secretary's authority in promulgating regulations in the manner the City suggests.

In the NLEA, Congress delegated broad authority and instructions to issue regulations to implement subsection (r). Thus, subsection (r)(2)(A)(i) anticipates that the Secretary would issue regulations defining "terms." In addition, section 3(b) of the NLEA provides an expansive instruction that the Secretary "shall issue proposed regulations to implement section 403(r) of the Federal Food, Drug, and Cosmetic Act, [21 U.S.C. § 343(r)]" and that such regulations "(i) shall identify claims described in section 403(r)(1)(A) of such Act which comply with section 403(r)(2) of such Act, [and] (iv) shall permit statements describing the amount and percentage of nutrients in food which are not misleading and are consistent with the terms defined in section 403(r)(2)(A)(i)." Pub. L. No. 101-535, § 3(b), 106 Stat. 4501. Surely in identifying "claims" described in subsection (r) that "comply with" the NLEA and in permitting "statements describing the amount...of nutrients in food" that are "not misleading" and that are "consistent with terms defined in [the NLEA]," the FDA was well within its statutory authority to specify the manner in which such claims and statements could be presented to consumers.

Other provisions of the NLEA confirm that Congress intended and expected that the FDA would promulgate regulations governing the manner in which nutrition information is presented to consumers. See, e.g., § 343(r)(2)(A)(ii) (allowing the Secretary to make regulations permitting a statement about the absence of a nutrient if the Secretary finds it would assist consumers in maintaining healthy dietary practices); § 343(r)(7)(A)(ii) (allowing the Secretary to expedite effectiveness of proposed

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regulations if necessary to allow actions on petitions that would provide for information necessary to "enable consumers to be informed promptly and effectively of important new knowledge regarding nutritional and health benefits of food."). In addition, section 343(r)(2)(G)(iv) provides that even if the Secretary has not promulgated regulations under (r)(2), a claim of the type described in (r)(1)(A) may be made, provided the claim is "stated in a manner . . . so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of the total daily diet." See also 21 U.S.C. § 343(r)(2)(G)(iv) (similar language concerning health claims).

E. Contrary to the City's Argument, Restaurant Menu Boards Are Included Within the Statute's Definition of "Labeling"

It is well-established that menus and menu boards are food "labeling" under the NLEA and therefore are subject to requirements of the NLEA and accompanying FDA regulations. *See Shalala*, 932 F. Supp. at 16. "Labeling" is defined under the FDCA as "all labels and other written, printed or graphic matter . . . accompanying such article." 21 U.S.C. § 321(m). The term "accompanying such article" is broadly construed, encompassing any item that "supplements or explains [the article] No physical attachment one to the other is necessary. It is the textual relationship that is significant." *Kordel v. United States*, 335 U.S. 345, 350 (1948). Accordingly, "accompanying' has

⁹ To the extent the Court deems the statute to be silent on the extent of the statutory delegation, such silence must be resolved in favor of agency authority to regulate. See Nat'l Cable & Telecommunications Ass'n v. Brand X Internet Services, 545 U.S. 967, 980 (2005); Chevron, 467 U.S. at 842-48.

¹⁰ The NLEA amended the FDCA by adding sections 403(q) and (r) and 403A. Thus, the FDCA's definition section, 21 U.S.C. § 321, applies to subsection (r).

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been given a broad interpretation and comprises any materials which are intended to make claims or refer to a product, regardless of whether they accompanied the product in time or in presence, on in neither." *United States v. Diapulse Mfg. Corp. of Am.*, 269 F. Supp. 162, 165 (D. Conn. 1967) (citations omitted).

The FDA interprets food "labeling" expansively to include menus. See 61 Fed. Reg. 40320 ("Thus, the FDA concludes that the menu exemption [the exemption of restaurant menus that the FDA originally adopted] is not consistent with the congressional intent in adopting the 1990 amendments, and that there is no basis for exempting menus from coverage of [the NLEA].") Judge Friedman came to the same conclusion in Shalala, 932 F. Supp. at 16 (holding that menus are food labeling subject to NLEA). This treatment is consistent with other kinds of food "labeling" governed by the NLEA. Brochures and websites are food "labeling" subject to the NLEA. See, e.g., Reyes, 2006 WL 3253579, at *4 (nutrition information on brochures and websites "labeling" subjecting McDonald's to NLEA). In-restaurant signs, posters, brochures, notebooks and charts are labeling as well. 21 CFR § 101.10 (approving 21 CFR § 101.45 as a method of presenting nutrition information for restaurants). As the FDA has correctly noted, it is "virtually impossible to distinguish menus from the other types of restaurant labeling, such as signs, placards and other point of purchase information." 58 Fed. Reg. 33056 (June 15, 1993) (citing 58 Fed. Reg. 2302, 2387 and 58 Fed. Reg. 2478, 2516 (Jan. 6, 1993)).

II. REGULATION 81.50 VIOLATES THE FIRST AMENDMENT RIGHTS OF PLAINTIFF'S MEMBERS

The parties have suggested three possible lines of relevant cases under which

Regulation 81.50 might be evaluated under the First Amendment:

- 1. If Regulation 81.50 is properly analyzed under the line of cases dealing with "compelled speech" culminating in *United States v. United Foods*, *Inc.*, 533 U.S. 404 (2001), the City and its *amici* effectively concede that Regulation 81.50 cannot survive scrutiny.
- 2. If the Regulation, instead, must be analyzed under the intermediate scrutiny ordinarily applied to commercial speech, see Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York, 447 U.S. 557 (1980), the City and amici do not concede the point, but they make no serious effort to defend the Regulation. See Def. Br. 26 n.21 (addressing Central Hudson in a footnote).
- 3. That is why the City and amici argue so vehemently that the case must be evaluated only under a line of cases assessing "disclosure requirements." Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio, 471 U.S. 626 (1985); Nat'l Elec. Mfrs. Ass'n v. Sorrell, 272 F.3d 104 (2001). Regulation 81.50 would not survive even if it were so evaluated because there is a complete disconnect between an asserted interest in "disclosure" and what this Regulation actually says and does. In any event, neither Zauderer nor Sorrell should govern this case, for four reasons. First, unlike the state laws at issue in those cases, Regulation 81.50 is constitutionally suspect because it has actually chilled speech. See Riley v. Nat'l Fed'n of the Blind of N.C., Inc., 487 U.S. 781 (1988). Second, Regulation 81.50 is not a necessary element to further a regulatory regime that makes certain conduct unlawful. Third, Regulation 81.50 requires restaurants to convey a point of view not their own and with which they disagree. Fourth,

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the disclosure of otherwise hidden factual information.

A. Regulation 81.50 Impermissibly Compels Speech

Regulation 81.50 turns a proposal to enter into a transaction—"Bacon-Cheese-burger Deluxe, \$2.99"—into a message about the health effects of that transaction: "Bacon-Cheeseburger Deluxe, 1,000 cal., \$2.99." The First Amendment does not permit state laws that compel speakers to voice messages dictated by the government. *See* Pl. Br. 20-21. This is a "fundamental rule" of First Amendment protection: the government cannot usurp a speaker's "autonomy to choose the content of his own message." *Hurley v. Irish-American Gay, Lesbian and Bisexual Group of Boston*, 515 U.S. 557, 573 (1995). Free speech protections of the highest order forbid the government from conveying its own message out of the mouth of an unwilling speaker, even a commercial speaker. As the Supreme Court held in *United Foods*, First Amendment values are put at "serious risk" even by a law "compel[ling] a particular citizen, or a discrete group of citizens, to pay special subsidies for speech on the side that it favors[.]" 533 U.S. at 412. This is an *a fortiori* case: Regulation 81.50 requires Plaintiff's members to "utter the speech itself." *Id.* at 413.

Amici attempt to distinguish United Foods on the ground that Regulation 81.50 does not involve "association between or among" restaurants and does not "mandate assessments of monies for advertising[.]" Brief of Jennifer L. Pomeranz of the Rudd Center for Food Policy and Obesity et al. ("Pomeranz Br.") 16. These distinctions actually highlight the Regulation's incompatibility with free speech. Under Regulation 81.50, individual restaurants are themselves required to convey the City's message, with which they disagree. See infra pp. 24-27. In contrast, United Foods concerned the

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indirect injury of forced contributions to a group advertisement. As the Court itself recognized in *United Foods*, forcing speech (as here) is *worse* than the injury in *United Foods*, where the plaintiff was "required simply to support speech by others, not to utter the speech itself." 533 U.S. at 413. The Supreme Court struck down the assessment at issue in *United Foods* as incompatible with the First Amendment.¹¹

The City and *amici* also attempt to distinguish this case from *United Foods* on the theory that no "message" has been forced on the restaurants subject to Regulation 81.50. Def. Br. 21; Pomeranz Br. 14-15. The law, they argue, merely requires the posting of "factual information which [affected restaurants] have already chosen to publicly disclose elsewhere" and, as a result, has nothing to do with the expression of a particular viewpoint. *Id.* But how can the City seriously contend that no "message" is intended? Under the City's Regulation, the menu board—the restaurants' most important tool for communicating with its customers—will unmistakably say to customers that if you want to buy this hamburger, you must consider the health aspects of the purchase and that in doing so the single fact to consider is the calorie count. *Cf. Int'l Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67, 71-72 (2d Cir. 1996) (plaintiffs opposed law requiring labeling disclosure of rBST growth hormone in milk on the ground that "it compel[led] them 'to convey a message regarding the *significance* of rBST use that is expressly contrary to

¹¹ One of Defendants' amici contends, in an article, that United Foods is a "seriously misguided" case, "a mistake of the first magnitude," and "in serious tension with Zauderer." Robert C. Post, Transparent and Efficient Markets: Compelled Commercial Speech and Coerced Commercial Associations in United Foods, Zauderer, and Abood, 40 Val. U. L. Rev. 555, 557, 575-7 (2006). That view may have animated amici's advice to this Court. Nonetheless, the Supreme Court has not withdrawn from United Foods or from the way it limited Zauderer in United Foods. See infra p. 37. It is the law of the land.

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their views'") (emphasis added; internal quotations omitted).

The City's own submissions in this case demonstrate that conveying the City's health message is, in fact, the entire purpose of the Regulation. In recounting the history of the provision, Commissioner Frieden explained that "although consideration was given to requiring that more of the available nutritional information be posted, a *choice was made* to *focus on calorie information*[.]" Frieden Decl. ¶ 8 (emphasis added). The Regulation requires the posting of only caloric content, thereby conveying to consumers a message concerning the singular importance of calories in nutritional decisionmaking.

Plaintiff's members disagree with Dr. Frieden's opinion. To take just one example, Ms. Haugen of Burger King Corporation explains:

BKC strongly disagrees with New York City's regulation which requires it to isolate and post calorie information on menu boards in its restaurants. As most nutritionists know, overemphasis on any one nutrient such as calories can interfere with consumers obtaining a healthy, varied diet. Rather, BKC believes that nutrition information must be provided within the broader context of what it means to have a healthy diet, with an emphasis on consumers acquiring an energy balance while moderating intake of nutrients such as sodium, fats, trans fats and cholesterol....

While calories are important, we disagree with the message that the New York regulation requires us to communicate to our customers. Limiting the information on menu boards to a single nutrient as a guideline to the healthfulness of a particular food is misleading and can cause consumers to make the wrong food choice for themselves....

Requiring BKC to publish calorie count of foods alone and in isolation on the menu boards will undermine our carefully developed program to communicate nutrition information to our customers.... Customers will attribute to BKC the message that calories are the most important nutrient and that a single calorie number is all they need to know. While this may be the City's desired message, it is not the message that BKC wants to convey or with which it agrees....

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We do not agree with the message [Regulation 81.50] will force us to send to our customers. We believe it will undermine the nutritional message that we have carefully developed and chosen to send to our customers.

Haugen Decl. ¶¶ 14-18; accord DeMuth Decl. ¶¶ 14, 18; Liewen Decl. ¶¶ 4, 8; Richardson Decl. ¶¶ 5; LeClair Decl. ¶ 5.

The City does not challenge the *bona fides* of these opinions or the good faith in which they are held. In view of this uncontroverted testimony, we do not understand how the City can legitimately argue that a menu board complying with Regulation 81.50 conveys no message at all. Regulation 81.50 compels restaurants to convey the City's message to the detriment of their own lawful opinions, desires and views.

The City and *amici* implicitly acknowledge the content-based nature of Regulation 81.50 by arguing that Plaintiff's members could try to counter the City's message by "post[ing] additional information and even a *disclaimer* if they so choose." Def. Br. 21 (emphasis added); Pomeranz Br. 14 ("If restaurants have the point of view that additional nutritional information is important for consumers to receive at the point of purchase, Health Code § 81.50 leaves them free to communicate this *viewpoint* and to provide whatever *additional data* they wish to their customers.") (emphasis added). In so arguing, the City and their *amici* ignore the practical burden imposed by the remedy they propose. As evidenced by the City's various illustrations of "compliant" menu boards, even integrating calorie information *alone* results in cramped, cluttered, and confused menu boards. *See*, *e.g.*, Frieden Decl. ¶ 65. "Curing" the Regulation's burden by adding complete nutritional information to menu boards—in the typeface and size compelled by Regulation 81.50—would be both a practical impossibility and a further, substantial impediment to restaurants' communication with their customers.

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Moreover, the City's "disclaimer" suggestion belies a fundamental misperception of the protection afforded by the First Amendment. It would not have cured the constitutional violation in *Wooley v. Maynard*, 430 U.S. 705 (1977), for the plaintiff to add an "I'm a pacifist" bumper sticker as a "disclaimer" to the "Live Free or Die" motto on his license plate. It would not have cured the violation in *West Virginia Board of Education v. Barnette*, 319 U.S. 624 (1943), for the plaintiff to conclude, following his pledge of allegiance, with a "disclaimer" of "I don't actually believe this." And it would not have cured the violation in *United Foods*, 533 U.S. at 411-13, for the plaintiff to have taken out its own branded advertisements, nor in *International Dairy*, 92 F.3d at 71-72, for the plaintiff to have added a disclaimer to its milk labeling contending that rBST is perfectly safe. Simply put, the City's offer of "disclaimers" and "additional information" does not cure the constitutional violation; and in fact it highlights the message-based nature of the Regulation.

B. Regulation 81.50 Cannot Survive Review Under Central Hudson

Even if Regulation 81.50 did not fail as "compelled speech," it would fail under the test for commercial speech enunciated in *Central Hudson*. Under the standard set out in *Central Hudson*, governmental burdens on commercial speech are subject to a fourpart inquiry asking: (1) whether the expression concerns lawful.activity and is not misleading; (2) whether the asserted governmental interest is substantial; (3) whether the challenged law directly advances the asserted interest; and (4) whether the challenged law is not more extensive than is necessary to serve the asserted interest. 447 U.S. at 566. The City does not allege that the menus or menu boards of those restaurants subject to Regulation 81.50 are misleading, much less that they concern unlawful activity. *See* Def.

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Br. 26 n.21 (stating, in the context of *Central Hudson*, that "[t]here is no dispute as to the first two prongs"). ¹² For its part, Plaintiff has acknowledged that the City's asserted interest—protecting the public health—is a substantial one. The parties diverge, however, on *Central Hudson*'s other tests.

1. Regulation 81.50 Does Not Directly Advance The City's Asserted Interest In Curbing Obesity

To survive scrutiny under *Central Hudson*, the City must prove that Regulation 81.50 advances the government's asserted, substantial interest in a "direct and material way." *Edenfield v. Fane*, 507 U.S. 761, 767 (1993). This burden cannot be met by "speculation or conjecture": the constitutional interests at stake require the government to "demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree." *Id.* at 770-71. "Without this requirement, a State could with ease restrict commercial speech in the service of other objectives that could not themselves justify a burden on commercial expression." *Id.* at 771.

While documenting the ills of obesity, see, e.g., Frieden Decl. ¶¶ 3-4, 9-22, the
City provides only speculation and conjecture with regard to how the particular
Regulation at issue would be effective in reducing obesity, relying on leaps of faith. The
City's reliance on speculation is unsurprising. First, as previously argued, the studies
cited by the Department in promulgating its Regulation merely note the "potential"
benefits of providing consumers with nutritional information. See Pl. Br. 26-27. The
City does not and cannot argue that these studies prove that its Regulation "will in fact"

¹² The City's concession that restaurants subject to Regulation 81.50 have not engaged in misleading speech or speech that concerns unlawful activity is equally significant under *Zauderer*, discussed *infra* pp. 35-37.

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alleviate the harms of obesity "to a material degree." See Edenfeld, 507 U.S. at 771.

Of particular interest here, Dr. Frieden's extensive declaration devotes only two paragraphs to the effectiveness of the Regulation. Frieden Decl. ¶¶ 49-50. These paragraphs are filled with words that bespeak hypotheses, not conclusions based on evidence—"suggest," "supposing," "assume," "likely." *Id.* Even if the Regulation had no effect on consumer food choices, "it is likely to increase the number of lower-calorie...offerings these facilities provide." *Id.* ¶ 50. This is conjecture upon conjecture; it is not based on any evidence. That is why Dr. Frieden himself concludes only that Regulation 81.50 has a "potential for public health impact." *Id.* ¶ 49.

This defense of the Regulation's effectiveness glosses over a great number of unanswered questions. The Keystone Forum Final Report (to which Dr. Frieden and *amici* look for support) explains:

There is a clear need for more research regarding how the provision of nutrition information, claims (such as "low calorie"), and symbols influence consumer preference and choice for away-from-home food consumption situations. Of particular concern is how, when, and why consumers use nutrition information and claims during their decision-making processes. More specifically, a better understanding is needed of the types of factors that moderate consumers' responses to the provision of nutrition information and claims for away-from-home foods.

Keystone Forum on Away-From-Home Foods: Opportunities for Preventing Weight Gain and Obesity, Final Report, at 83-84 (May 2006). The Final Report then suggested many "research questions" that needed answering, including "What type of information should be provided?.... How and where should information be provided, given the goals for providing such information? At point of sale, before sale, after sale for future purchases, etc.? Via menu board, brochure, table tent, poster, kiosk, etc.? If the information is

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accessed, how is it used? Under what circumstances is current behavior influenced and under what circumstances is future behavior influenced? For example, if consumers consume an extra 100 calories at lunch, will they eat a lighter dinner?.... Is information on the caloric content of food items more likely to be used by the consumer when presented alone or when embedded in general nutrition content information?" Id.

All these questions are unanswered, not only by the City, but by the state-of-theart research available. As the Keystone Forum Final Report put it,

> Better and more timely information is needed regarding: the choices consumers are making regarding foodservice venues and foods, the values and motivations driving those choices, the factors that motivate changes in behaviors and attitudes, the potential value of nutrition information and other specific interventions, and the best ways to promote changes in products or menus that are relevant to weight management....

> Evidence regarding how and why consumers use nutrition information is limited. Outstanding questions include how consumers process and use such information, what measurable contribution the information can make to the goal of managing weight gain and obesity, where the point of decision-making is for away-from-home-foods consumers, and what effect information may have on consumer choice, eating behavior, and store revenue. Likewise lacking are data with regard to whether one format or another alters the rate of consumer usage of the information.

Id. at 46, 69; see id. at 22 ("The research base on obesity is incomplete and imperfect regarding some aspects of the problem, such as the potential effectiveness of specific interventions aimed at assisting consumers with managing their energy intake."); id. at 67 (listing as a "Basic Research Need" information on "What information, if any, regarding the nutritional composition of menu items prompts consumers to take action and choose items to manage weight?").

Dr. David Allison, whose declaration is submitted with this Memorandum, has done a review of the literature and of the specific articles upon which the City has previously relied. *See* Allison Decl. 17-18. Based on that review, he has concluded that it is possible to conjecture that Regulation 81.50 would be effective in meeting its goals, or that it would be ineffective, or that it would be positively harmful. *Id.* 24.

None of this is to say that speculation and conjecture are irrelevant to public policy. Although the kind of speculation and conjecture involved here might be sufficient to support certain government initiatives—for example, providing educational literature to city residents, or teaching good health practices in schools, or encouraging restaurants voluntarily to provide customers with certain information—it is insufficient to support a coercive governmental program burdening the First Amendment rights of those regulated. That is the core meaning of the third prong of *Central Hudson*.

2. Regulation 81.50's Infringement On Speech Is More Extensive Than Necessary To Serve The City's Asserted Interest

Even when a governmental burden on speech is effective to a material degree, it must still employ a means "narrowly tailored to achieve the desired objective." *Lorillard Tobacco v. Reilly*, 533 U.S. 525, 556 (2001) (internal quotations omitted). In this case, there are many alternatives for providing customers with caloric information in restaurants that would not so heavily burden restaurants' First Amendment rights by coopting their most important communication tool and using it to convey a message with which they disagree. These alternatives include signs directing consumers to comprehensive nutritional information, posters with complete nutritional information, food wrappers with such information, counter-mats with such information, stanchions

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and flip-charts with such information, and prominently displayed brochures. See Horn Decl. ¶ 2-4; Colón Decl. ¶ 8-9; Keystone Forum Final Report App. J at pp. 128-33 (listing alternatives including websites, server-delivered information, second menus, health-oriented menu sections, health-related symbols for menus, tray liner information, packaging information, reference books, posters, handouts, brochures). Signs directing consumers to nutritional information elsewhere in a restaurant could be placed prominently on or near menu boards. Moreover, the City clearly anticipates customers making repeated visits to those restaurants subject to the ordinance; so any caloric information reviewed even after the time of purchase would inform the patron during later visits. Regulation 81.50, however, bars alternatives that do not "display[] calorie information at least as prominently as calorie information would otherwise be displayed using the format proscribed by section 81.50(b)(1)." Colon Decl. Ex. D. The City does

C. Zauderer And Sorrell Are Inapplicable

not even attempt to defend this failure at narrow tailoring.

The City and its amici devote their briefs to the contention that Regulation 81.50 is merely a "disclosure requirement" subject to "reasonableness" review under Supreme Court's decision in Zauderer and the Second Circuit's decision in Sorrell.

The City relies most heavily on Zauderer. There, the State required that contingency-fee lawyers disclose to unsophisticated contingency-fee clients that they might have to pay litigation costs if their claims proved unsuccessful. 471 U.S. at 650. The Court explained that "an advertiser's rights are adequately protected as long as disclosure requirements are reasonably related to the State's interest in preventing deception of consumers." 471 U.S. at 651 (emphasis added).

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In Sorrell, the Second Circuit applied Zauderer and upheld a statute that barred the dumping of products containing mercury and, to effect that ban, required sellers to "inform the purchaser or consumer that mercury [was] present in the item and that the item [could] not be disposed of or placed in a waste stream destined for disposal until the mercury is removed and reused, recycled, or otherwise managed to ensure that it does not become part of solid waste or wastewater." 272 F.3d at 107 n.1.

Zauderer and Sorrell are inapplicable here, for at least four reasons. First, Regulation 81.50 is not a disclosure requirement at all; because it does not apply to those who choose not to disclose, it has actually chilled protected speech. Second, the Regulation is not an adjunct to a broader regulatory regime that makes certain conduct unlawful, as in Sorrell. Third, Regulation 81.50 bears on controversial speech and for that reason cannot be analogized to the "purely factual" and "non-controversial" disclosure at issue in Sorrell. Fourth, the Regulation cannot be justified as reasonably related to the prevention of consumer deception—the touchstone of Zauderer as limited by United Foods.

1. Regulation 81.50 Has Chilled Speech

Regulation 81.50, in purpose and in effect, does not actually advance the disclosure of any new information at all. To the contrary, the record is uncontroverted that Regulation 81.50 has actually chilled disclosure. See Frieden Decl. ¶ 36; Burnett Decl. ¶ 4; Richardson Decl. ¶ 4. This actual chilling of lawful and indeed desirable speech is powerful evidence that the City has gone too far: "unjustified or unduly burdensome disclosure requirements might offend the First Amendment by chilling protected commercial speech." Zauderer, 471 U.S. at 651; see Riley, 487 U.S. at 794.

The City and its amici ask this Court to turn a blind eye to the uncontroverted

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evidence that speech has in fact been chilled by Regulation 81.50; their theory is that, in general, commercial speech is "less likely than other forms of speech to be inhibited by proper regulation." *See Friedman v. Rogers*, 440 U.S. 1, 10 (1979); Def. Br. 27; Pomeranz Br. 18. But given the durability of commercial speech, the evidence of actual chilling stands as powerful testament to the City's overreaching here.

The Regulation has driven some restaurants to withhold the caloric content of their food from consumers. Moreover, the Regulation creates a powerful incentive now for restaurants that do not provide nutritional information to their customers to continue to remain silent for all time. The "marketplace of ideas" has been impoverished, rather than enhanced. See Sorrell, 272 F.3d at 114 ("disclosure furthers, rather than hinders, the First Amendment goal of the discovery of truth and contributes to the efficiency of the 'marketplace of ideas'"). By infringing certain restaurants' First Amendment rights, in other words, Regulation 81.50 effectively deprives consumers of information. Zauderer and Sorrell do not support such a provision.

2. Regulation 81.50 Does Not Prevent Unlawful Conduct

Regulation 81.50, unlike the law at issue in *Sorrell*, is not an adjunct necessary to implement a law that makes certain activity unlawful. In *Sorrell*, Vermont had made unlawful the dumping of mercury-containing products together with ordinary waste. It would have been virtually meaningless to pass such a law without also providing

¹³ In arguing that Regulation 81.50 cannot chill speech because the provision applies to all restaurants that did not withdraw their nutrition disclosures before March 1, 2007, see Pomeranz Br. 18, amici overlook the fact that, at some point in time (past or future), each restaurant faced or will face a choice of "opting out," whether by withdrawing information before March 1, 2007 (see Frieden Decl. ¶ 36), or simply by choosing to remain silent now and in the future.

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consumers with information about which products were subject to this prohibition—information that was not otherwise known to them. Regulation 81.50 serves no analogous law-enforcement purpose. The distinction between laws mandating speech further to the context of a broad regulatory regime and those that do not was discussed at length in *United Foods*, 533 U.S. at 412-13.

3. Regulation 81.50 Does Not Limit Itself to Factual, Non-Controversial Information

Regulation 81.50 goes well beyond the documentation of uncontroversial information. Because Zauderer and its progeny focus on the prevention of deception, their reach is limited to "purely factual and uncontroversial information[.]" See Zauderer, 471 U.S. at 651. Sorrell, by its own terms, applies only to laws requiring disclosure of accurate, factual non-controversial information. As the Circuit acknowledged, a regulation "[r]equiring actors in the marketplace to espouse particular opinions would likely raise issues not [there] presented[.]" 272 F.3d at 114 nn.4-5.

Plaintiff's members vigorously dispute the City's point of view that informed nutritional decisions can be made by considering calories out of the context of other nutritional values. See supra pp. 25-26. The Keystone Forum, on which the City and amici rely, observed that "[t]he range of views on this topic, outlined here, may help the reader to understand the complexity of the issue and the diverse and sometimes strong views that the topic generates among stakeholders." Keystone Forum Final Report at 70.

The Second Circuit's decision in *International Dairy Foods Association* is instructive. There, the Court enjoined the enforcement of a Vermont law that required dairy producers to label all products made with rBST, a growth hormone used to treat

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dairy cattle. 92 F.3d at 69, 73. While the disclosure mandated by the statute was undoubtedly true as a factual matter, the law required milk producers "to convey a message regarding the significance of rBST use that [was] expressly contrary to their views." *Id.* at 71 (internal quotations omitted). The Second Circuit applied *Central Hudson* and struck down the law. *Id.* at 74.¹⁴

4. Regulation 81.50 Does Not Prevent Misleading Speech

Regulation 81.50 does not purport to protect against potentially misleading speech. The City justifies the regulation as a way of achieving the state's interest in reducing obesity. See Def. Br. 26 n.21. 15 Plaintiff certainly agrees that public health is a substantial governmental interest. That is not in dispute. But to further this interest, as opposed to the interest in preventing deceptive commercial speech, the City may not burden speech without meeting the standards of United Foods and Central Hudson.

The City and *amici* claim that *Zauderer* opened the door to any and all state disclosure requirements "regardless of why the disclosure of uncontroverted facts [was] being mandated." Def. Br. 19. But *Zauderer*'s identification of the "State's interest in preventing deception of consumers," 471 U.S. at 651, was not merely the fortuitous byproduct of the particular facts that happened to be before the Court. It was, rather, the necessary consequence of earlier decisions defining the boundary between misleading speech, which is not protected at all by the First Amendment, and commercial speech,

¹⁴ United Foods had not yet been decided when the Second Circuit decided International Dairy, so the court applied Central Hudson.

While the City and its *amici* suggest in passing that Regulation 81.50 addresses consumers' "inaccurate perceptions" regarding the caloric content of food, Def. Br. 26; Pomeranz Br. 11, they cannot seriously maintain that "Hamburger, \$1.99" is deceptive.

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which is protected.

The Court has long held that certain forms of "speech" are simply beyond the ambit of First Amendment protection. See Paris Adult Theatre I v. Slaton, 413 U.S. 49 (1973) (obscenity); Chaplinsky v. New Hampshire, 315 U.S. 568 (1942) (fighting words). Misleading commercial speech falls within this category. See In re R.M.J., 455 U.S. 191, 203 (1982) ("Misleading advertising may be prohibited entirely."); Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748, 771 (1976) (same). As one scholarly text explains, "certain commercial speech is not entitled to protection; the informational function of advertising is the First Amendment's concern and if an advertisement does not accurately inform the public about lawful activity, it can be suppressed." Johnny H. Killian, George A. Costello and Kenneth R. Thomas, The Constitution of the United States of America: Analysis & Interpretation, at 1180 (Sen. Doc. 108-17) (2002).

Thus, in developing First Amendment protection for commercial speech, the Supreme Court has expressly linked the validity of so-called "disclosure" requirements to their ability to protect against potentially misleading speech. As the Court explained in *Virginia State Board*, the state may regulate potentially "deceptive or misleading" commercial speech by "requir[ing] that a commercial message appear in such a form, or include such additional information, warnings, and disclaimers, as are necessary to prevent its being deceptive." 425 U.S. at 771 n.24. Similarly, the Court explained in *R.M.J.*, the state "may not place an absolute prohibition on certain types of *potentially* misleading information ... if the information also may be presented in a way that is not deceptive Although the potential for deception and confusion is particularly strong in

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the context of advertising professional services, restrictions upon such advertising may be no broader than reasonably necessary to prevent the deception." 455 U.S. at 203 (emphasis added); see also Rubin v. Coors Brewing Co., 514 U.S. 476, 494 (1995) (Stevens, J., concurring) ("[A]ny description of commercial speech that is intended to identify the category of speech entitled to less First Amendment protection should relate to the reasons for permitting broader regulation: namely, commercial speech's potential to mislead.").

The Zauderer case fits comfortably within this line of cases. It holds that a "disclosure requirement" affecting commercial transactions must protect against potentially misleading information. It has been so limited by the Supreme Court in United Foods, which rejected application of Zauderer to the law there at issue on the ground that there was "no suggestion" in United Foods "that the mandatory assessments imposed to require one group of private persons to pay for speech by others are somehow necessary to make voluntary advertisements nonmisleading for consumers." 533 U.S. at 416. We recognize that Sorrell rejected the limitation of Zauderer set forth in United Foods, but it is unclear how this aspect of Sorrell can be reconciled with United Foods.

In any event, Sorrell is distinguishable for the reasons discussed supra pp. 33-36.

D. The City's Parade of Horribles Is Not Real

The City contends that every disclosure statute or regulation on the books will be put in jeopardy if Plaintiff prevails. But each requirement the City and *amici* cite is either directed toward preventing deception or unlawfulness in commercial transactions, ¹⁶ is

¹⁶ See, e.g., 15 U.S.C. § 78l (registration requirements for securities, including anti-fraud disclosures); 21 U.S.C. § 343 (preventing misbranding in food); 21 C.F.R. § 202.1 (regulating drug advertisements to protect consumers from misleading advertisements); N.Y. Agric. & Mkts. Law § 214-h (requiring retail stores to disclose unit and total price information); 15 U.S.C. §§ 68 et seq. (requiring labeling of wool products' actual wool content, so as to [Footnote continued on next page]

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plainly subject to review under *Central Hudson* or even stricter scrutiny, ¹⁷ is necessary to prevent otherwise unlawful activity, ¹⁸ or does not concern commercial speech at all. ¹⁹ Significantly, neither the City nor its *amici* point to a single statute or rule that they believe would fail under the reading of *United Foods* or *Central Hudson* urged by Plaintiff but would be saved by their reading of *Zauderer*. Their parade of horribles is just a way to avoid focusing on what the Regulation at issue here actually says and what it actually does.

[[]Footnote continued from previous page]

protect consumers against concealment of substitutes for wool in products claimed to be made wholly or partially of wool, see Marcus v. FTC, 354 F.2d 85 (2d Cir. 1965)).

¹⁷ 2 U.S.C. § 434 (political committee receipts and disbursements, see McConnell v. FEC, 251 F. Supp. 2d 176 (D.D.C. 2003), aff'd in part, rev'd in part, 540 U.S. 93 (2003)); 15 U.S.C. § 1333 (cigarette labeling, see Lorillard Tobacco Co. v. Reilly, 533 U.S. 525); 27 U.S.C. § 205 (labeling of alcoholic beverages, see Rubin v. Coors, 514 U.S. 476); Cal. Health & Safety Code § 25249.6 (warnings of persons who will be intentionally exposed to carcinogens, see Baxter Healthcare Corp. v. Denton, 15 Cal. Rptr. 3d 430, 449 n.5 (Cal. Ct. App. 2004)).

¹⁸ See Sorrell, 272 F.3d at 107 n.1.

¹⁹ See, e.g., 33 U.S.C. § 1318 (preparation and filing of point source pollution discharge reports); 42 U.S.C. § 11023 (preparation and filing toxic chemical release reports); 29 C.F.R. § 1910.1200 (employer notifications of workplace chemical hazards); N.Y. E.C.L. § 33-0707 (submission of pesticide formulas to state commissioner).

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CONCLUSION

The Court should enter an order: (1) granting declaratory and summary judgment in favor of Plaintiff on its preemption claim, and (2) granting a preliminary injunction against enforcement of Regulation 81.50 pending a final adjudication of the merits.

Dated: July 20, 2007

New York, New York

Respectfully submitted,

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Counsel for Plaintiff, New York State Restaurant Association Case 1:07-cv-05710-RJH Document 46 Filed 07/20/2007 Page 49 of 49

CERTIFICATE OF SERVICE

I, Kent A. Yalowitz, the undersigned attorney at law duly admitted to practice in the State of New York, respectfully show that on the 20th day of July, 2007, the annexed REPLY MEMORANDUM IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION, DECLARATORY RELIEF AND PARTIAL SUMMARY JUDGMENT was served by hand delivery upon:

Mark W. Muschenheim Assistant Corporation Counsel Corporation Counsel of the City of New York 100 Church Street New York, New York 10007

Kent A. Yalowitz

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MANDATE

UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

NEW YORK STATE RESTAURANT ASSOCIATION,

Plaintiff-Appellee,

No. 07-4378-cv

NEW YORK CITY BOARD OF HEALTH, NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE, COMMISSIONER THOMAS R. FRIEDEN,

Defendants-Appellants.

5017 (NYC) 07-CV-5710 HOLWELL



STIPULATION AND ORDER

WHEREAS, on September 11, 2007, the District Court entered a Men orandum Opinion and Order holding that Section 81.50 of the New York City Health Code adorred on December 5, 2006 is without effect and permanently enjoining defendants from enforcing it; and

WHEREAS, defendants filed a Notice of Appeal on October 5, 2007 and

WHEREAS, the parties entered into a Stipulation and Order dated N wember 2, 2007 and filed November 14, 2007, which is attached and incorporated by reference herein; and

WHEREAS, the November 2, 2007 Stipulation and Order provides that "upon the adoption of a new Section 81.50, the parties agree that the above-captioned a peal will immediately be dismissed as most with prejudice by stipulation signed by the parties' counsel and without costs or attorneys fees incurred to date"; and

WHEREAS, on January 22, 2008, the New York City Board of Health repealed the former Health Code §81.50 and reenacted a new section 81.50.

1

CERTIFIED:



NOW THEREFORE, IT IS HEREBY STIPULATED AND AGREE by the undersigned counsel that:

The above-captioned appeal will be deemed dismissed as most with rejudice and without costs or attorneys fees incurred to date.

Dated: New York, New York January 23, 2008

MICHAEL A. CARDOZO Corporation Counsel of the City of New York Attorney for Appellants 100 Church Street New York, New York 10007 (212) 788-1034

Fay Ng
Assistant Corporation Counsel

ARNOLD & PORTER LP

Attorney for Appellee 399 Park Avenue New York, New York 1 2022 (212) 315-1000

Peter L. Zamroth

SO ORDERED:

FOR THE COURT

Catherine, O'Hagan Wolfe, Clerk of Court

By Stant a. Bus

Stanley A. Bass, Staff Counsel

Jan. 30, 2008